

LUX-Dx™

Case Collection



**THIS SIGNAL CHANGES
EVERYTHING**

Case Collection

Featured cases are from real LUX-Dx™ ICM Patients.

You can view the full report by clicking "View Report."

Event Report	Patient Monitored for:	Description of Event Report	View Report
Atrial Fibrillation	AF Management	AF with conversion pause <ul style="list-style-type: none"> Atrial fibrillation of 20-minute duration with an average ventricular rate of 86 bpm. A conversion pause at 1283 seconds (report page 6) with return to normal sinus rhythm. The rate plot clearly demonstrates the change from AF to NSR. 	View Report
	Syncope	AF caused by an aberrantly conducted PAC <ul style="list-style-type: none"> Atrial Fibrillation of 44-minute duration with an average ventricular rate of 112 bpm. Occasional PACs noted throughout the rhythm. Atrial beat hidden in the T-Wave at 212 seconds (report page 2). Short run of Atrial Tachycardia at 2781 seconds (report page 8). 	View Report
	AF Management	Two AF episodes showing atrial flutter with conversions to normal sinus rhythm <ul style="list-style-type: none"> Atrial flutter of 34-minute duration with an average ventricular rate of 86 bpm. The conversion to NSR is visible at 2138 seconds (report page 7). 	View Report
Pause	Syncope	High degree AV block detected <ul style="list-style-type: none"> At 7:04AM, a 3.7 second pause was detected. P-waves can be seen during AV block prior to the pause. P-waves are visible during the 3.7 second pause (report page 2). 	View Report
	Cryptogenic Stroke	4.8 second pause supported by the rate plot <ul style="list-style-type: none"> At 5:34AM, a 4.8 second pause was detected. In the rate plot, a heart rate drop is visible prior to and after the pause supporting a true pause. 	View Report
	Syncope	8.8 second pause <ul style="list-style-type: none"> At 5:00AM, an 8.8 second pause was detected. The beginning of the pause can be seen at 27 seconds (page 2). 	View Report
Tachycardia	Ventricular Tachycardia	PVC induced non-sustained VT and return to normal sinus rhythm <ul style="list-style-type: none"> Monomorphic VT episode lasting 13 seconds (22 beats) with an average ventricular rate of 192 bpm, max V rate of 203 bpm. Occasional PVCs noted throughout the event. 	View Report
	Syncope	SVT Event <ul style="list-style-type: none"> SVT episode lasting 6 minutes and 48 seconds with an average ventricular rate of 160 bpm, max V rate of 188 bpm. 	View Report
	AF Management	SVT episode and return to normal sinus rhythm <ul style="list-style-type: none"> SVT episode lasting 14 seconds (14 beats) with an average ventricular rate of 160 bpm, max V rate of 169 bpm. 	View Report
Atrial Tachycardia	Suspected AF	Sustained AT with regular V to V rhythm and consistent rate <ul style="list-style-type: none"> Atrial rate of 145 bpm during the 10 hour 16 minute AT episode. 	View Report
Bradycardia	Cryptogenic Stroke	P-waves during brady event <ul style="list-style-type: none"> At 11:34AM, bradycardia event with an average rate of 40 bpm over the 12 second duration of the event. 	View Report
	Cryptogenic Stroke	2:1 HB during brady event <ul style="list-style-type: none"> At 9:11PM, bradycardia event with an average rate of 37 bpm over the 5 second duration of the event. Clinic entered "2:1 HB" in the notes section. R-waves are clipped as the S-ECG is zoomed to see p-waves. 	View Report
Follow-Up	Cryptogenic Stroke	Presenting strip with P-waves	View Report
	Cryptogenic Stroke	P-waves in presenting strip for a patient with runs of AF <ul style="list-style-type: none"> Visible P-waves in the presenting S-ECG could make adjudicating the AF events easier 	View Report

PATIENT MONITORED FOR: AF Management

DETAILS:

AF with conversion pause

- Atrial fibrillation of 20-minute duration with an average ventricular rate of 86 bpm.
- A conversion pause at 1283 seconds (report page 6) with return to normal sinus rhythm.
- The rate plot clearly demonstrates the change from AF to NSR.
- AF settings were programmed to nominal.
- The first 3 minutes of this report shows the dashed line though the S-ECG as only the intervals are store per the storage guidelines above.
 - For S-ECG storage of an AF episode that's ≥ 2 minutes: Each AF event contains 3 minutes of intervals before the start, 1 minute of annotated S-ECG data after the start, and up to 3 minutes of annotated S-ECG at the end.

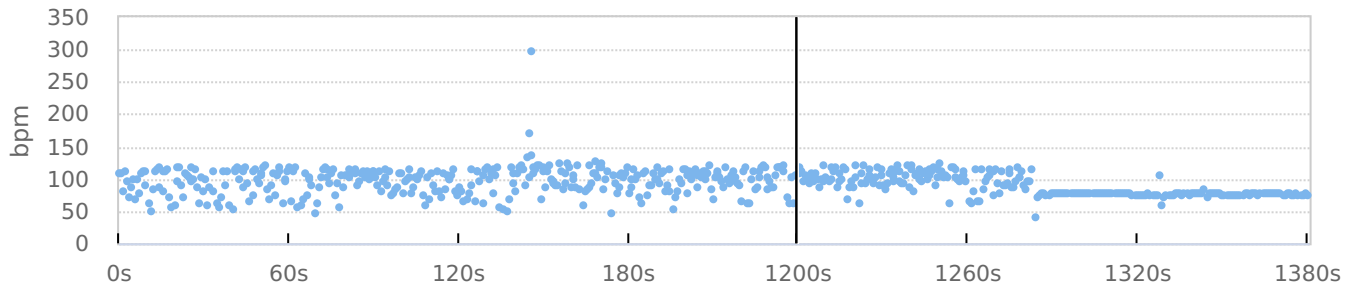


Reason For Monitoring
AF Management

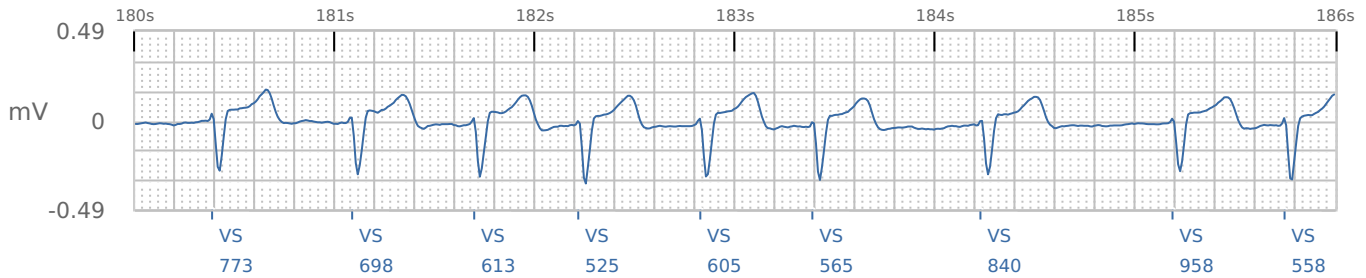
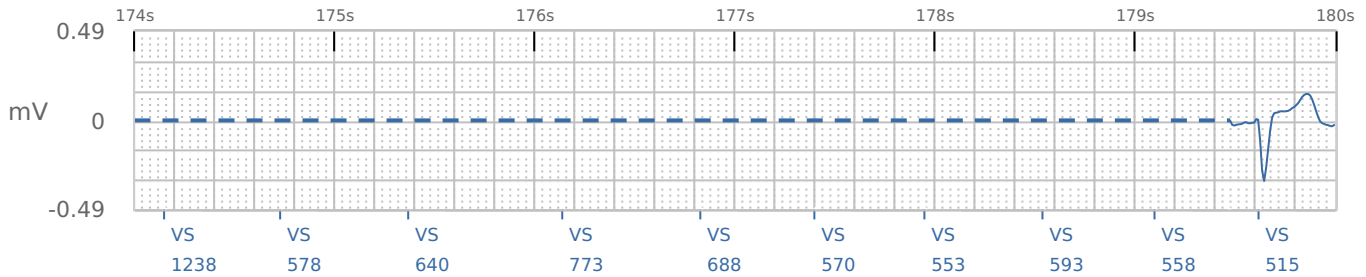
Clinical Context:
None

Event	Description	Date/Time	Duration	Rate	Assessment
AF-97	AF	Nov 11, 2020 03:18 EST	20 m 00 s	Avg 96 bpm Max 126 bpm	Appropriate

AF Settings
 Response Balanced
 Duration 10 min
 Morphology Assessment On



S-ECG displayed at 25mm per second



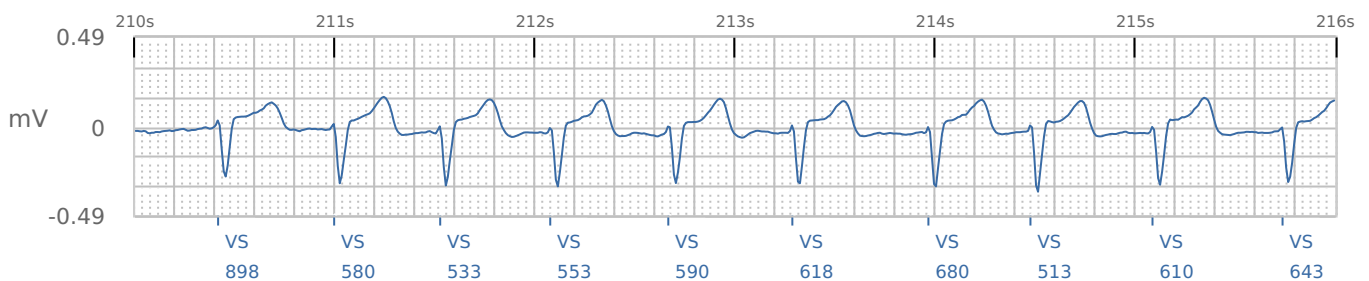
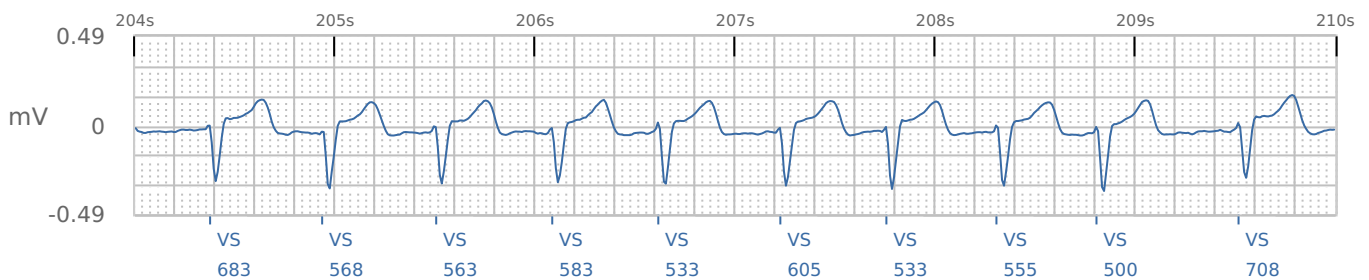
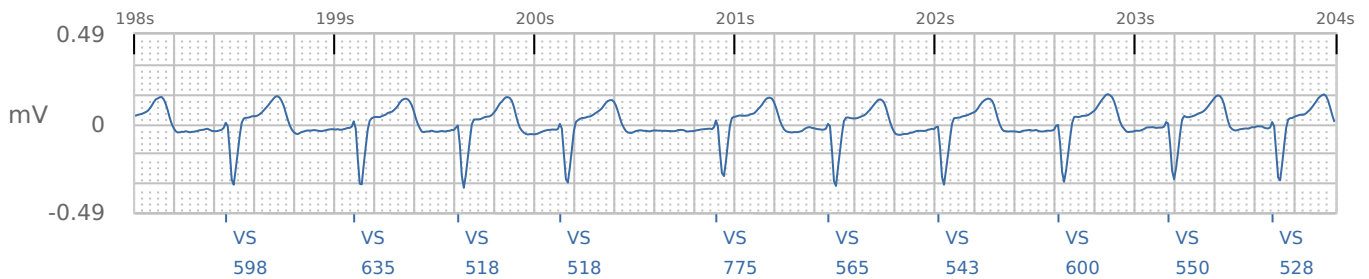
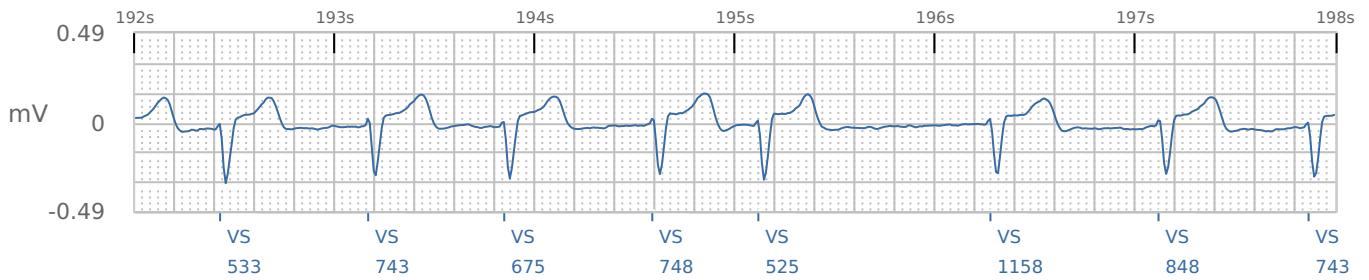
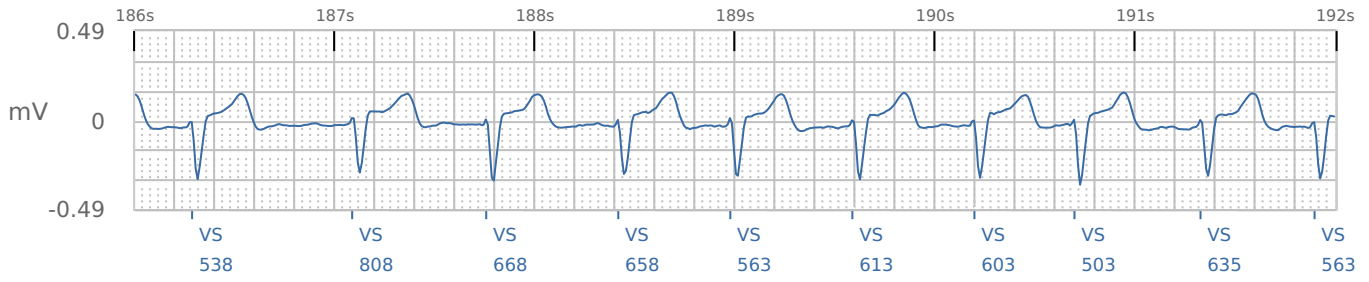
Comments & Interventions

Signature

Date

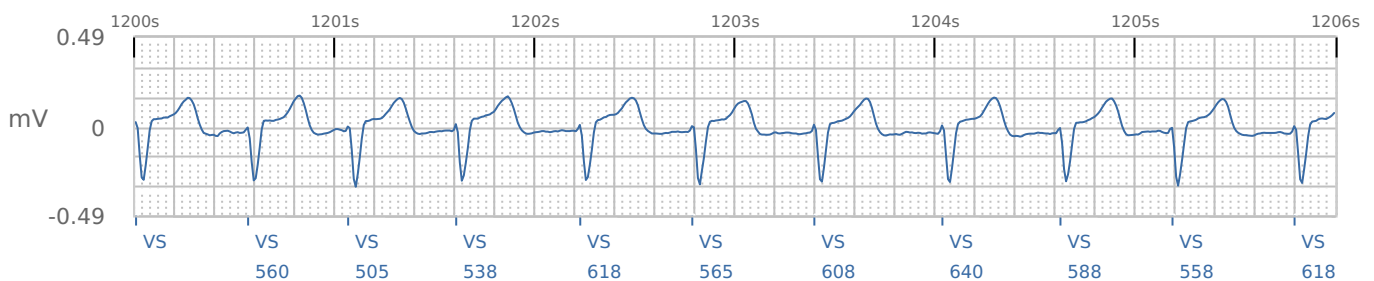
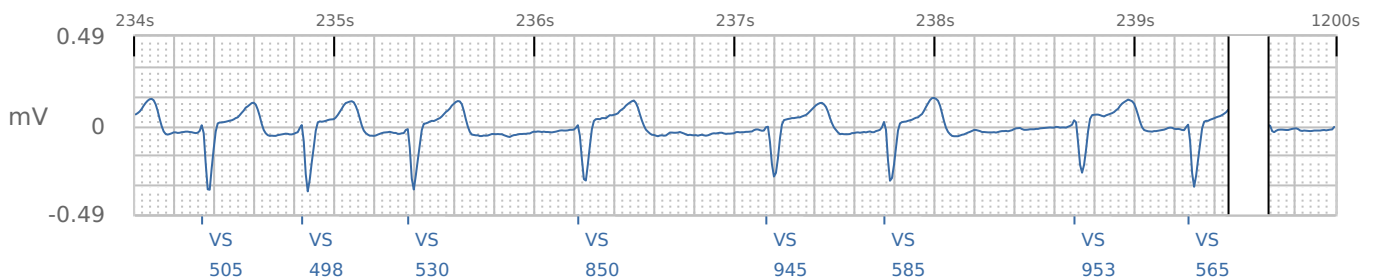
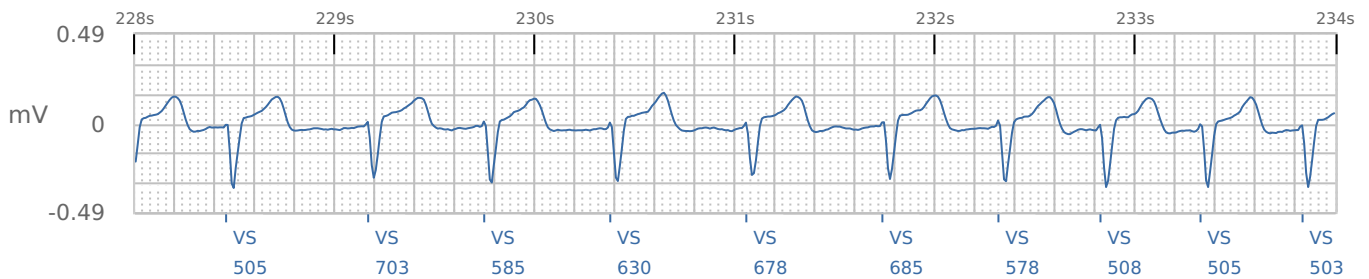
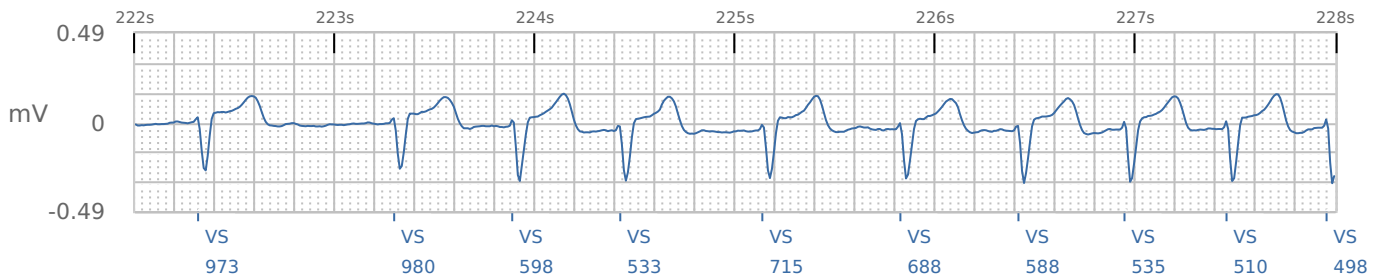
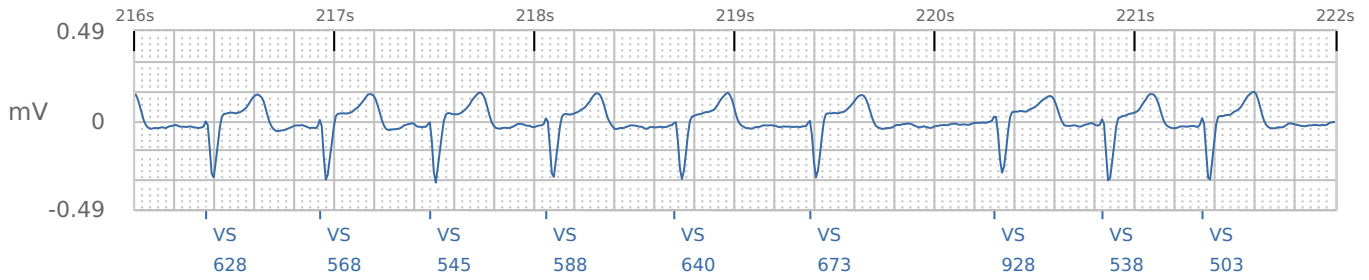
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Monitoring: AF Management



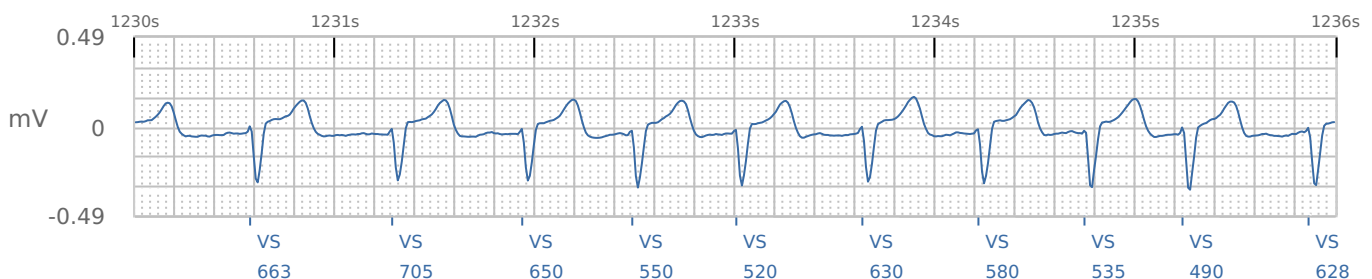
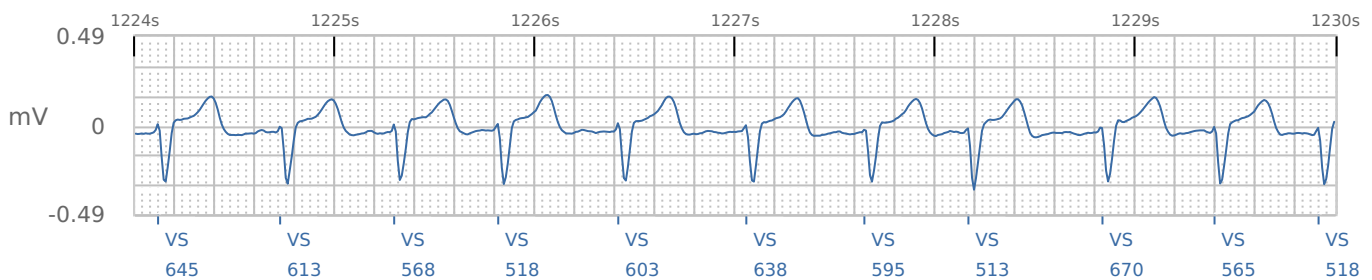
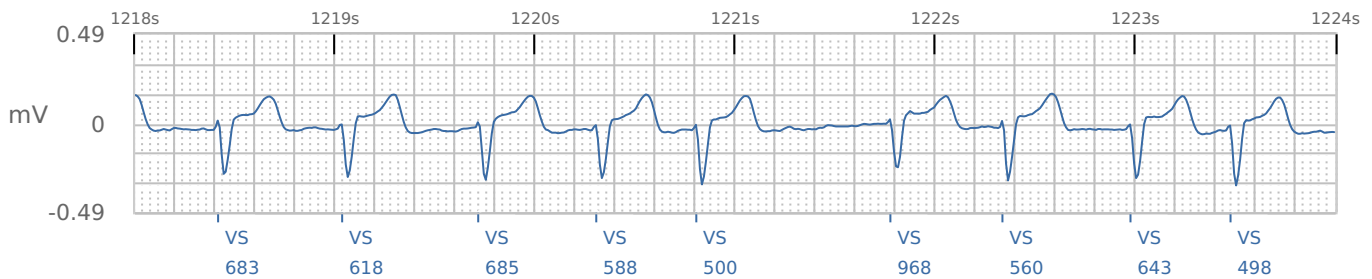
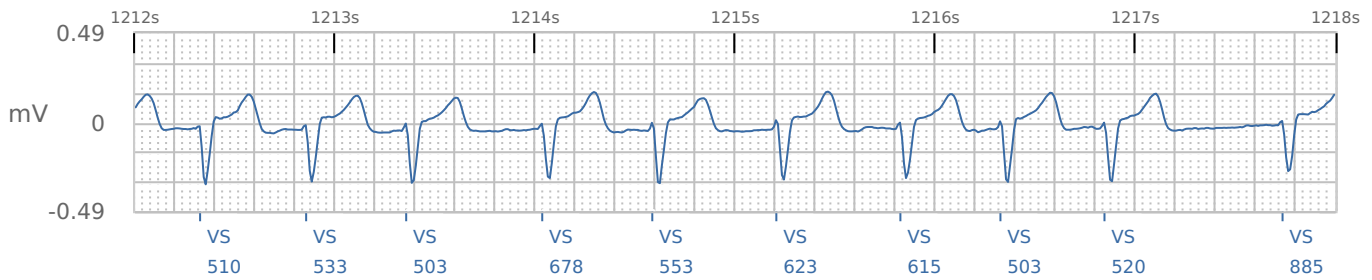
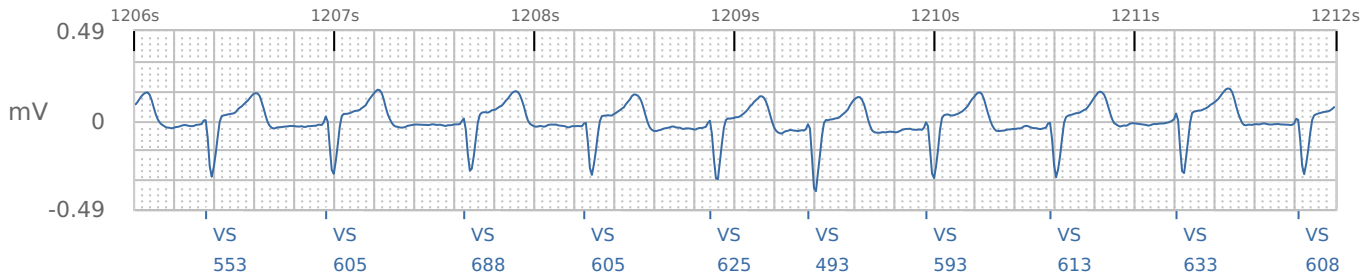
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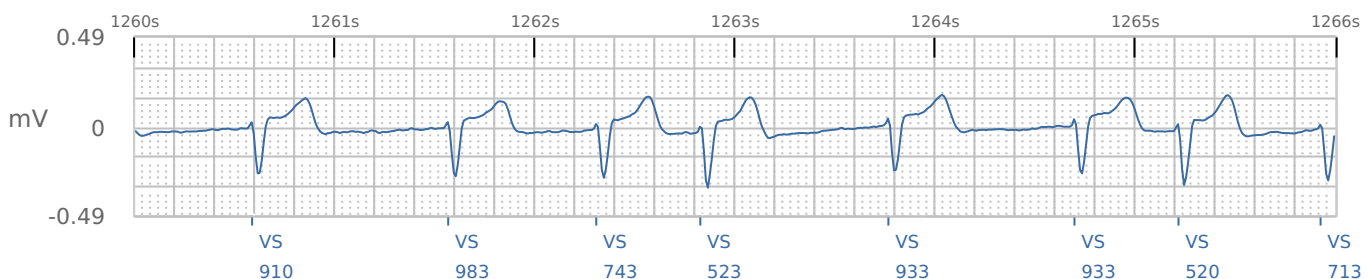
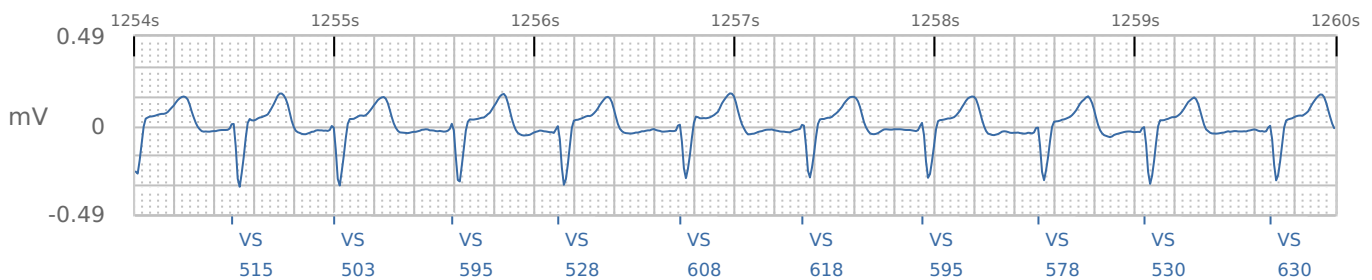
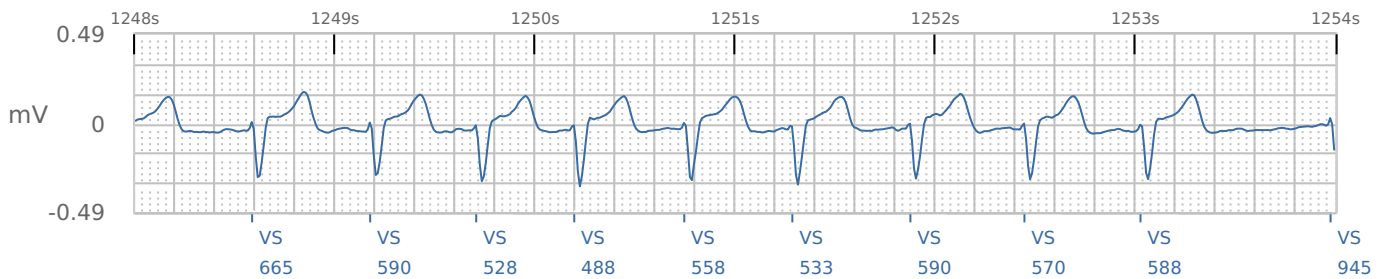
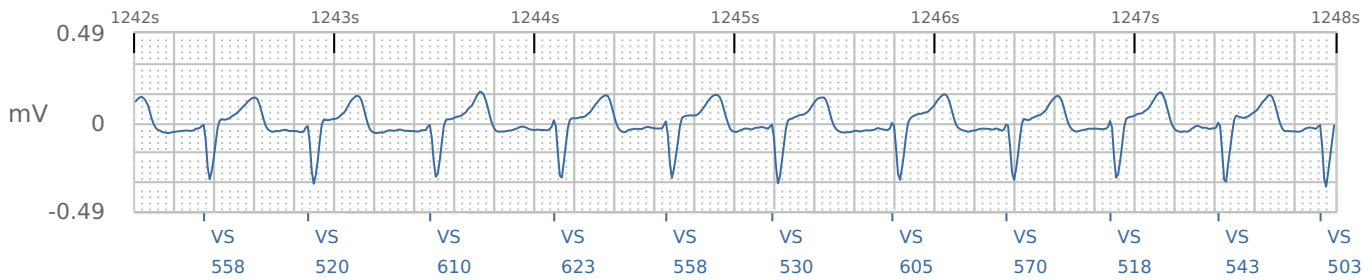
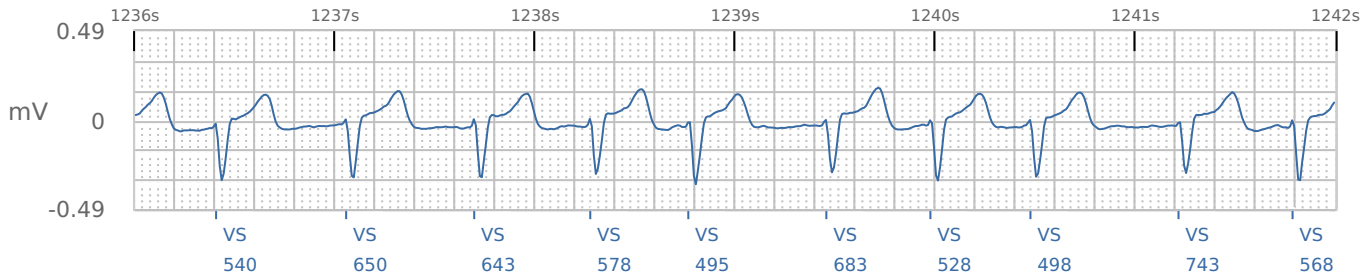
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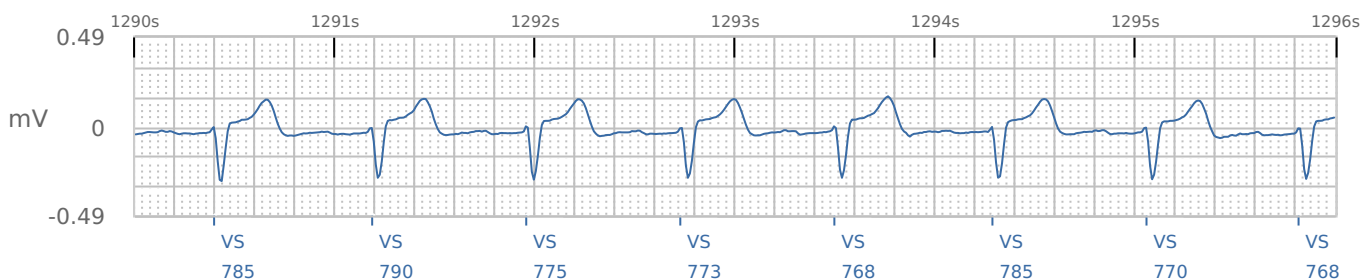
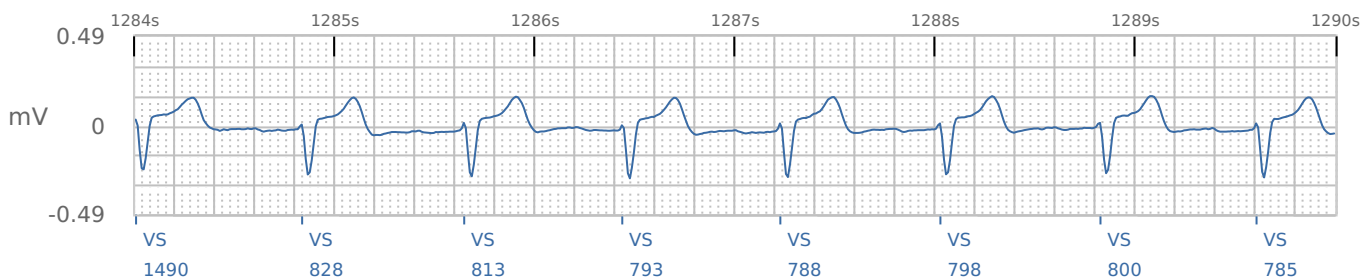
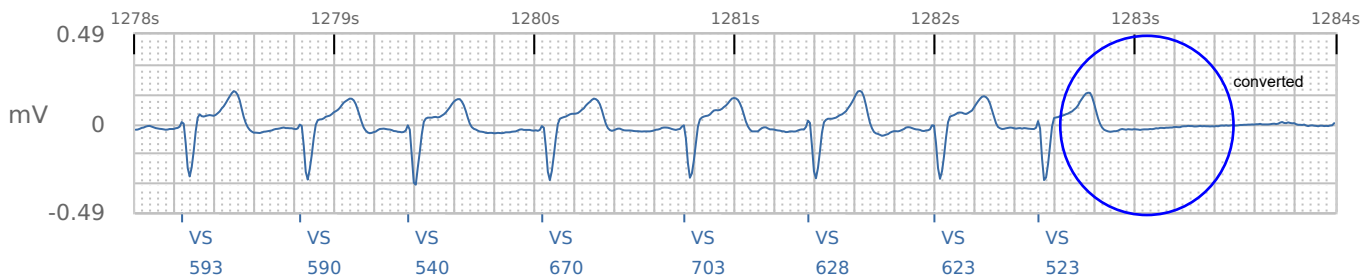
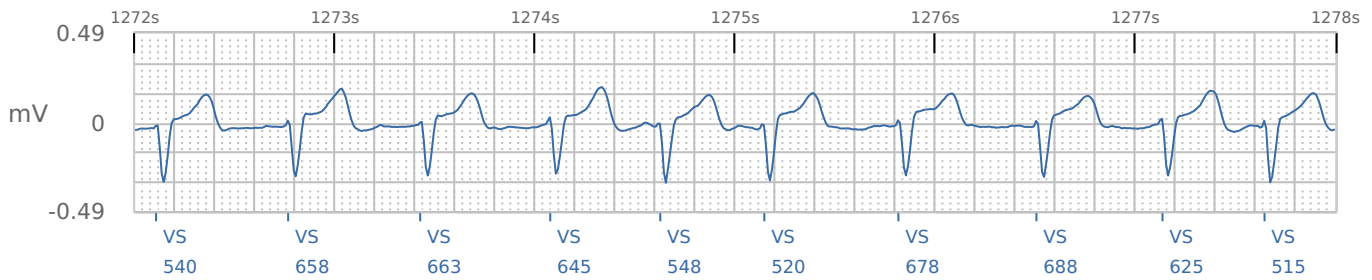
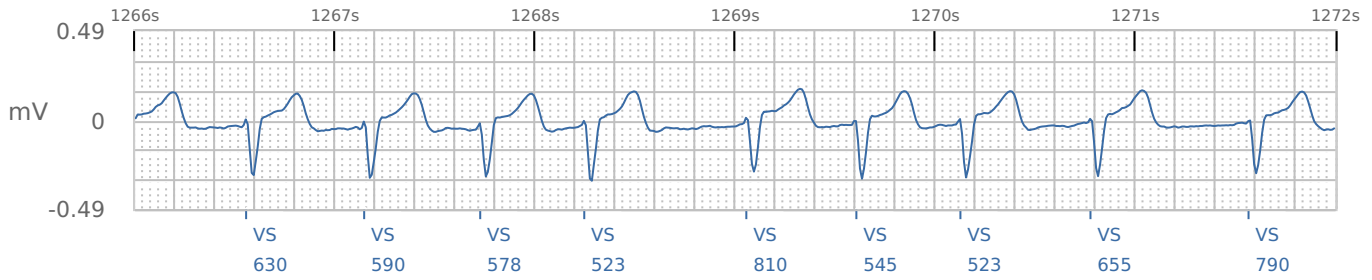
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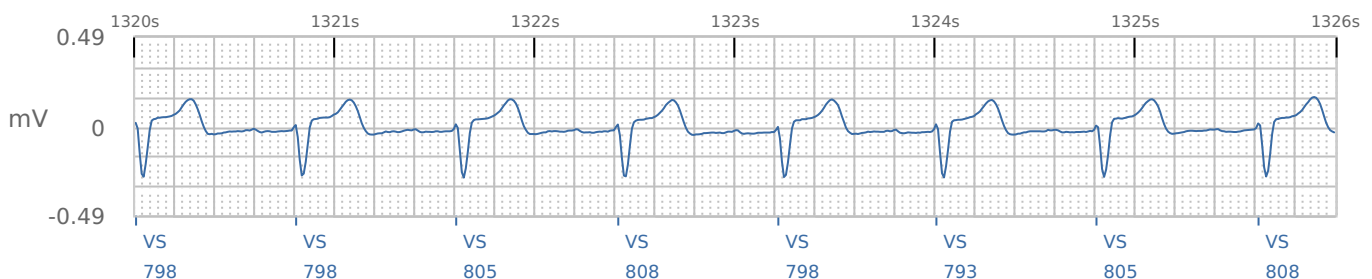
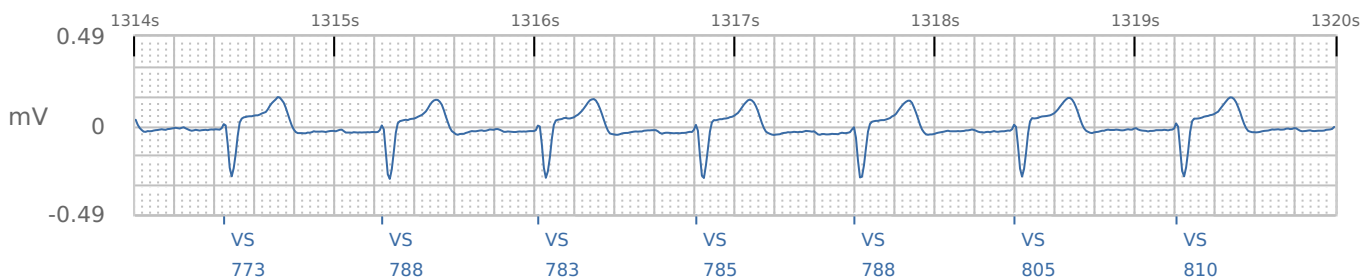
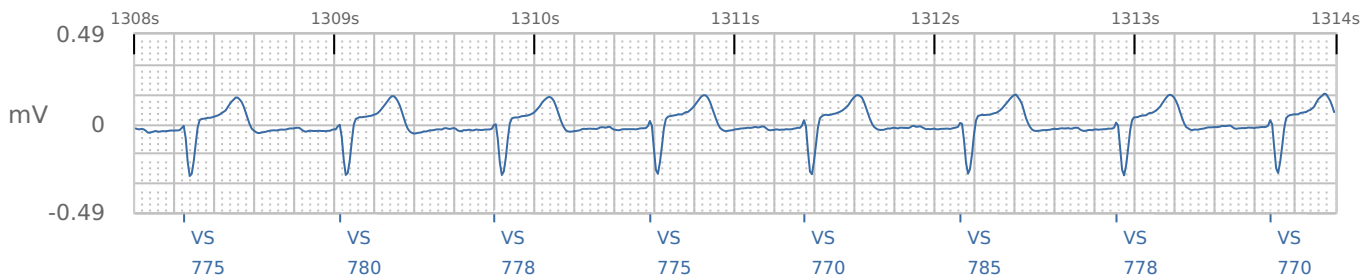
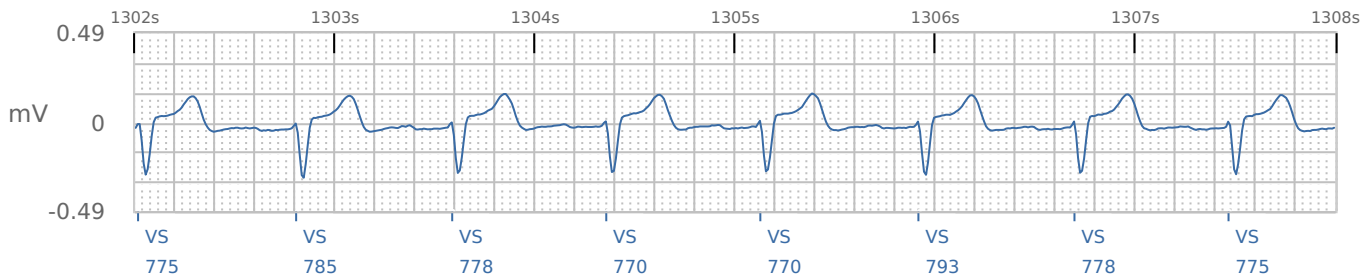
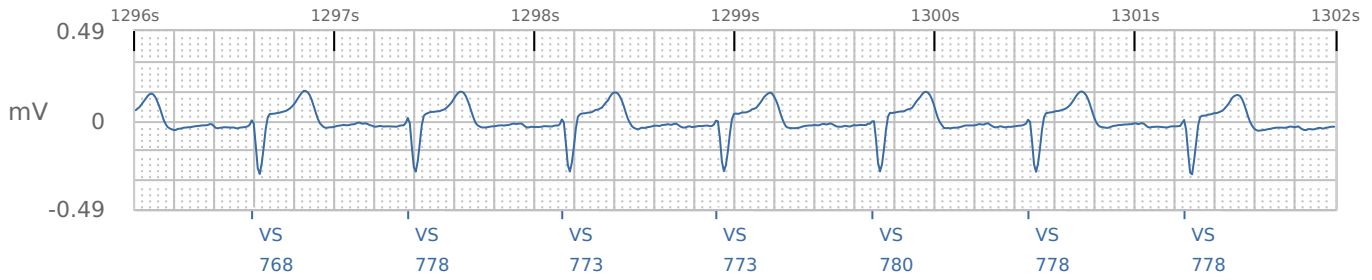
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Monitoring: AF Management



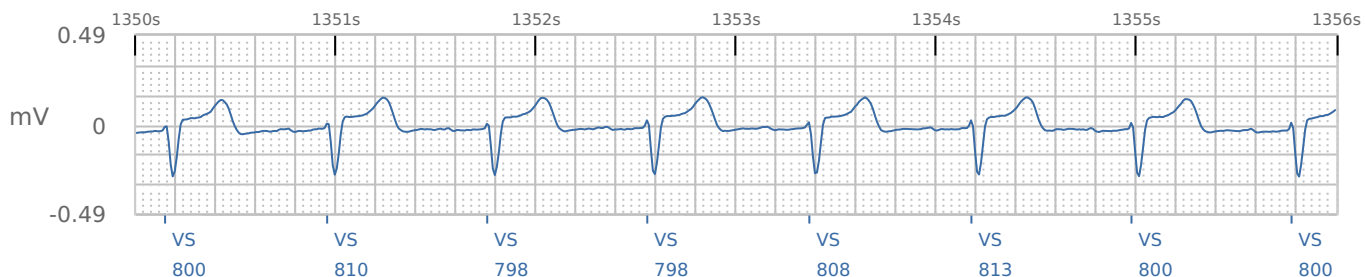
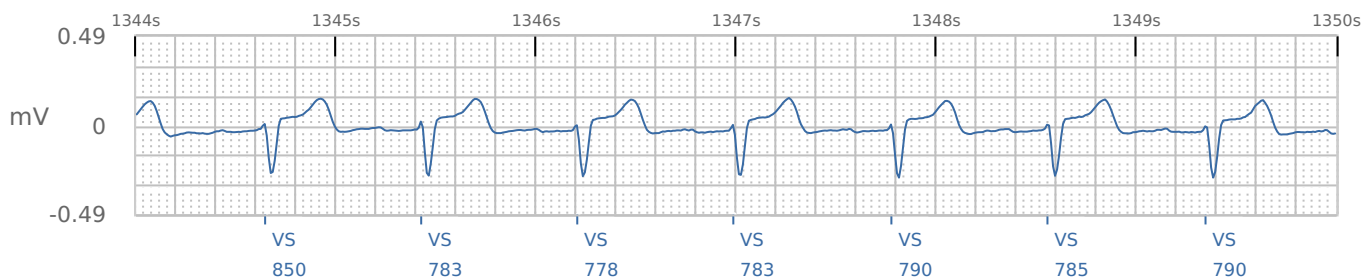
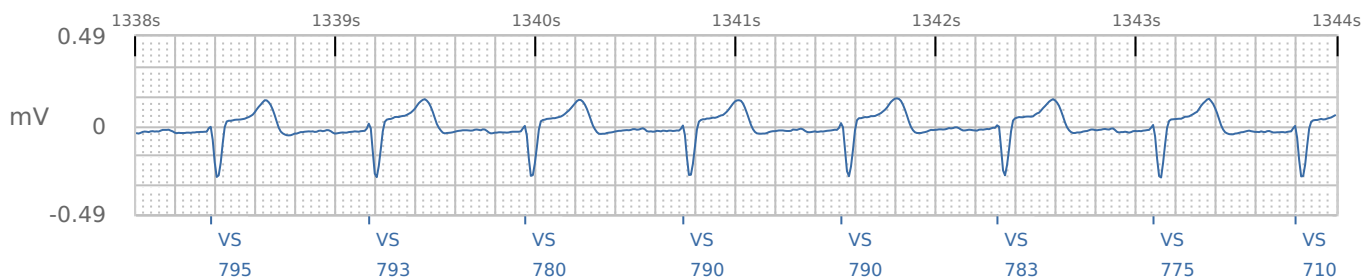
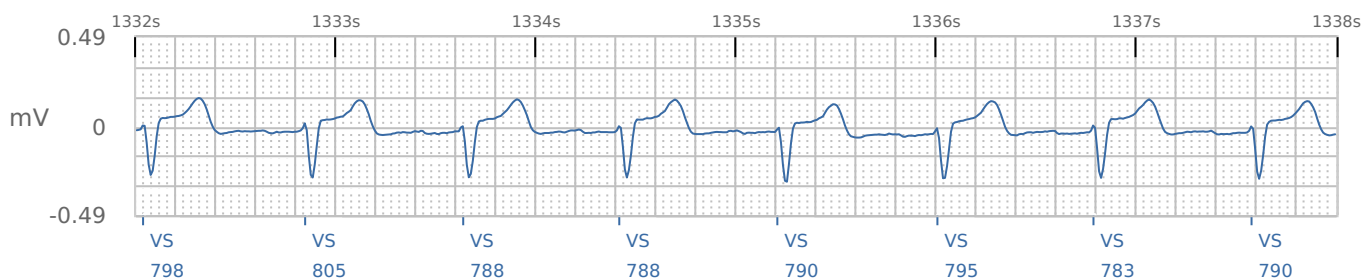
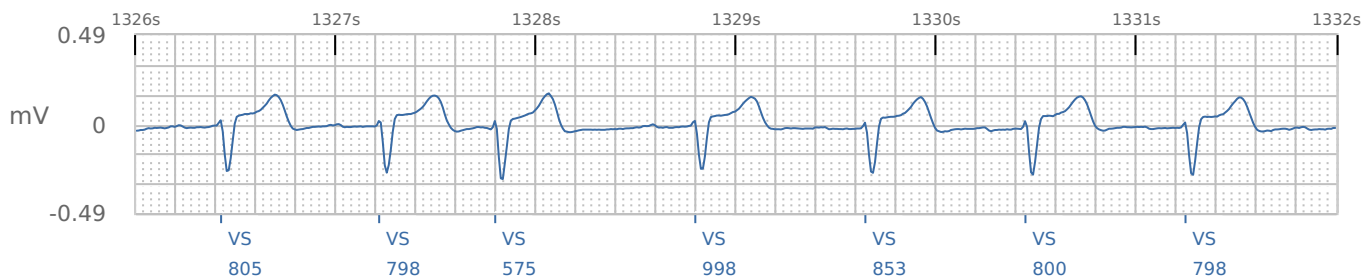
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Monitoring: AF Management



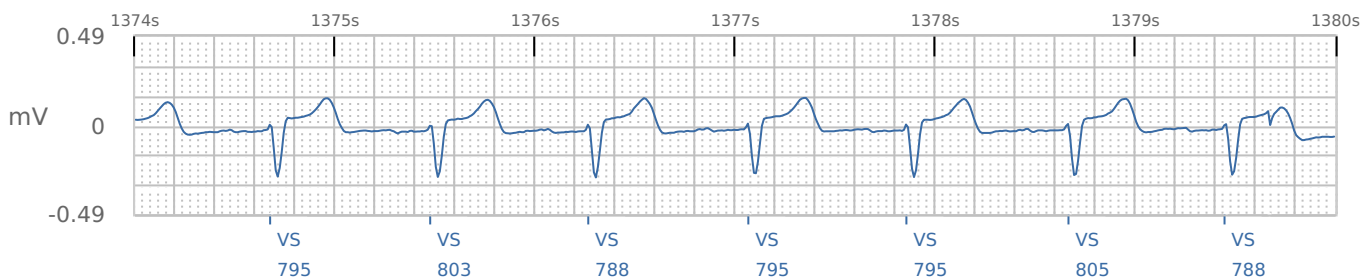
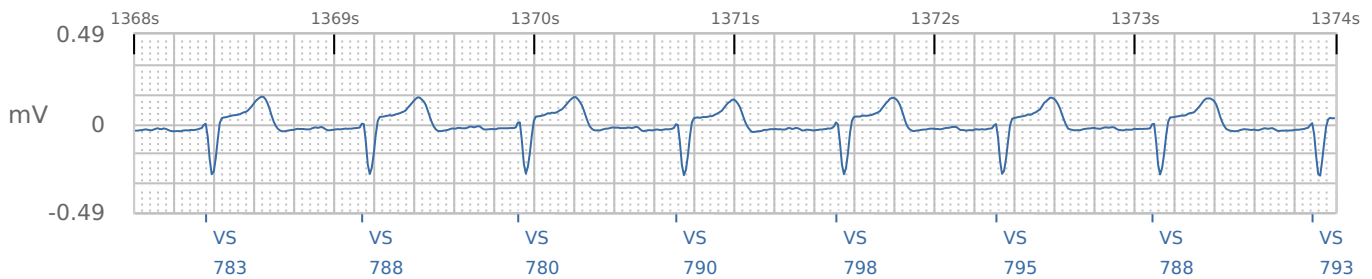
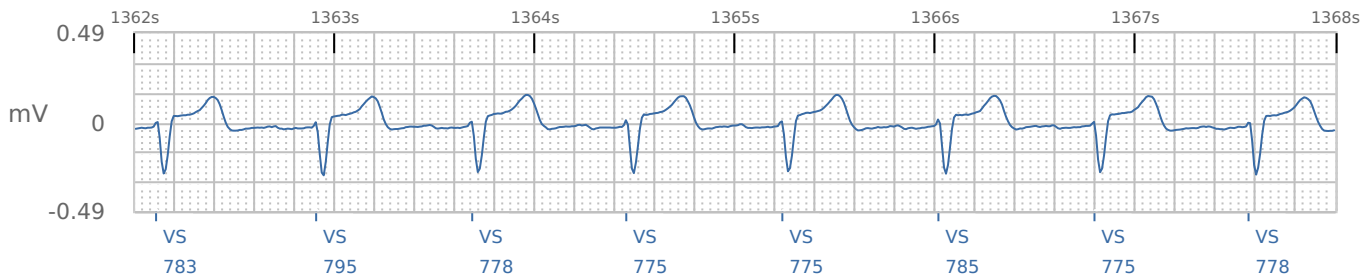
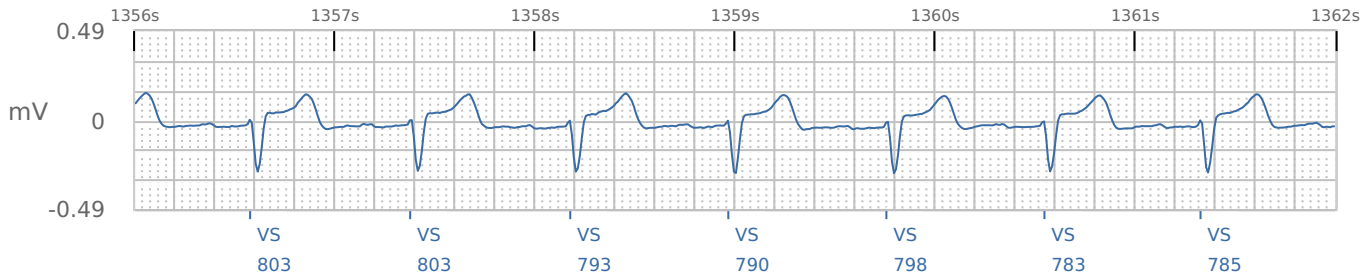
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Monitoring: AF Management

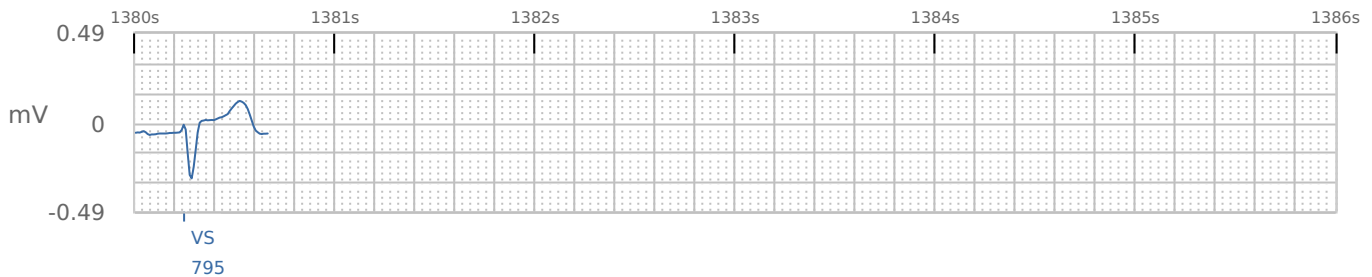


ID:

Monitoring: AF Management



End AF



PATIENT MONITORED FOR: Syncope

DETAILS:

AF caused by an aberrantly conducted PAC

- Atrial Fibrillation of 44-minute duration with an average ventricular rate of 112 bpm.
- Occasional PACs noted throughout the rhythm.
- Atrial beat hidden in the T-Wave at 212 seconds (report page 2).
- Short run of Atrial Tachycardia at 2781 seconds (report page 8).
- AF settings were programmed to nominal.

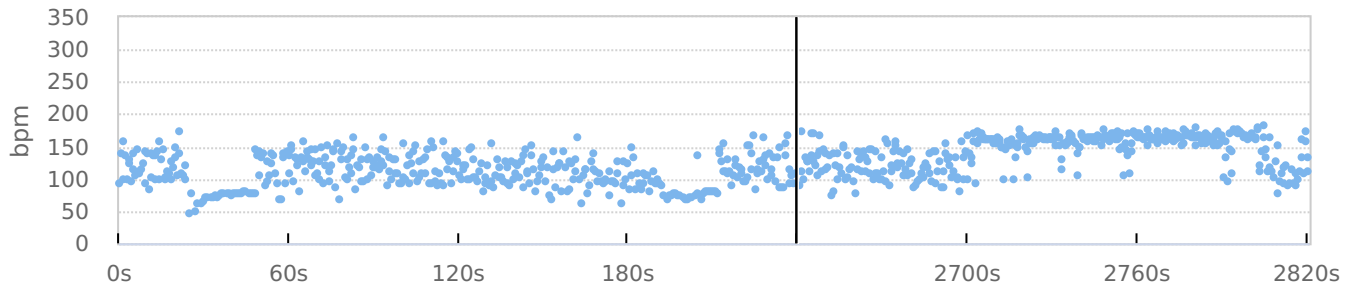


Reason For Monitoring
Syncope

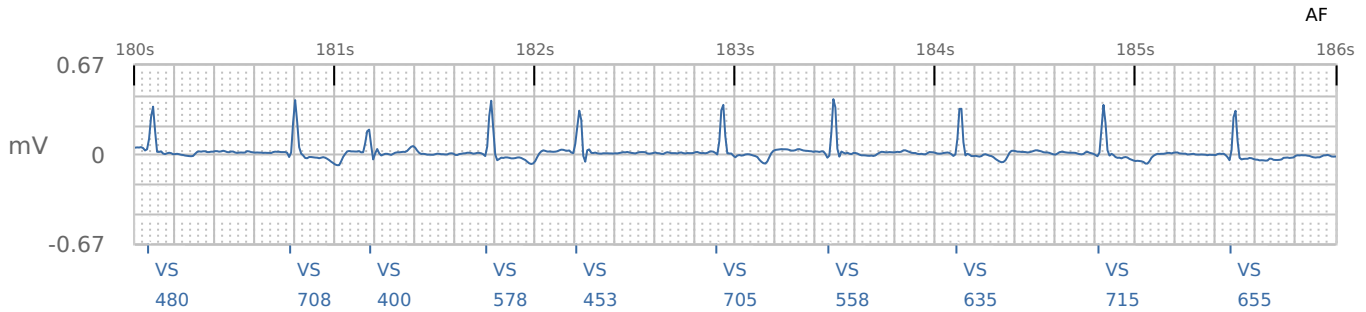
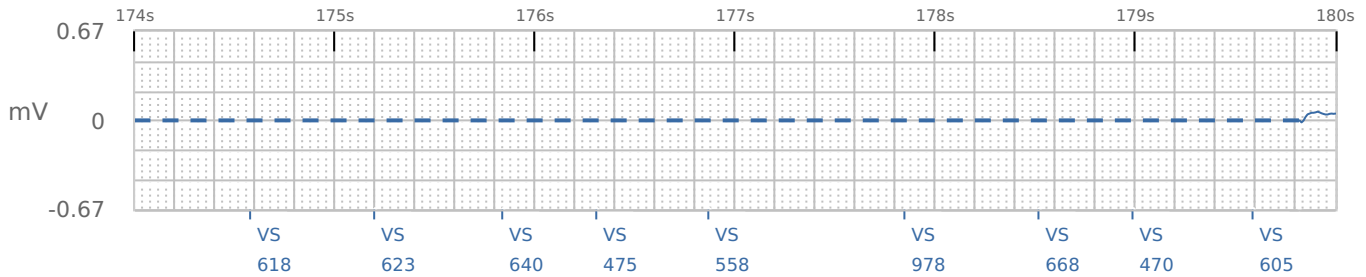
Clinical Context:
None

Event	Description	Date/Time	Duration	Rate	Assessment
AF-4	AF	Nov 27, 2020 11:04 EST	44 m 00 s	Avg 112 bpm Max 172 bpm	Not Assessed

AF Settings
 Response Less
 Duration 10 min
 Morphology Assessment On



S-ECG displayed at 25mm per second

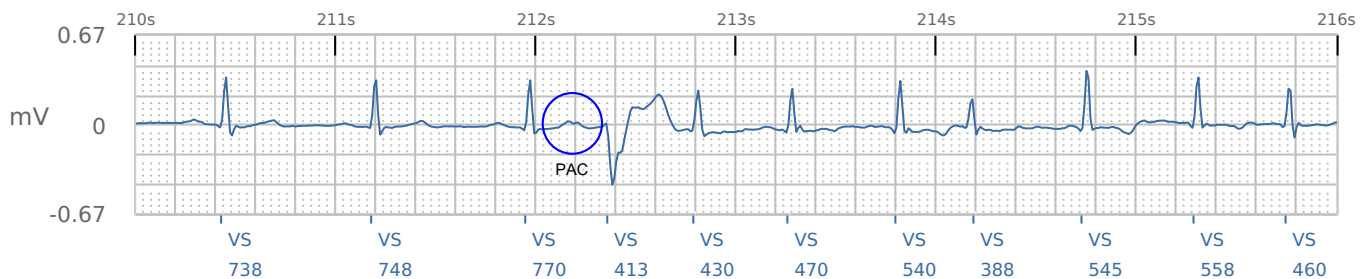
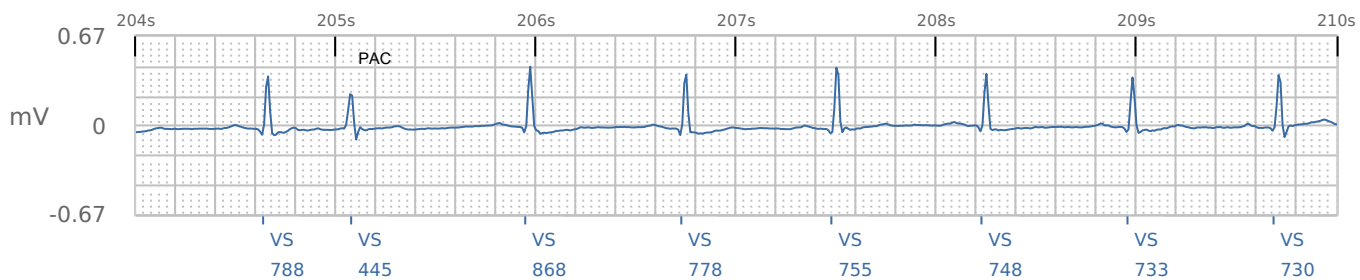
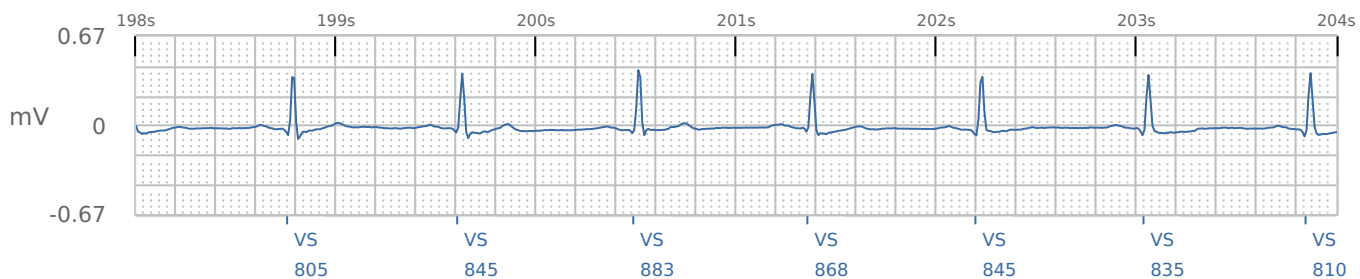
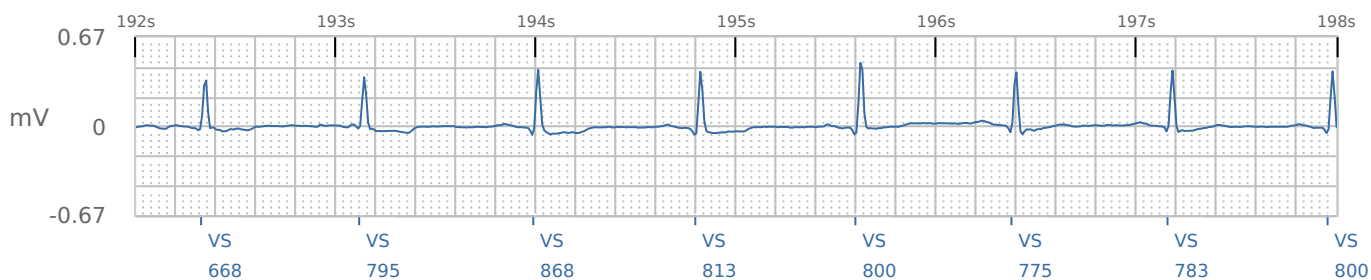
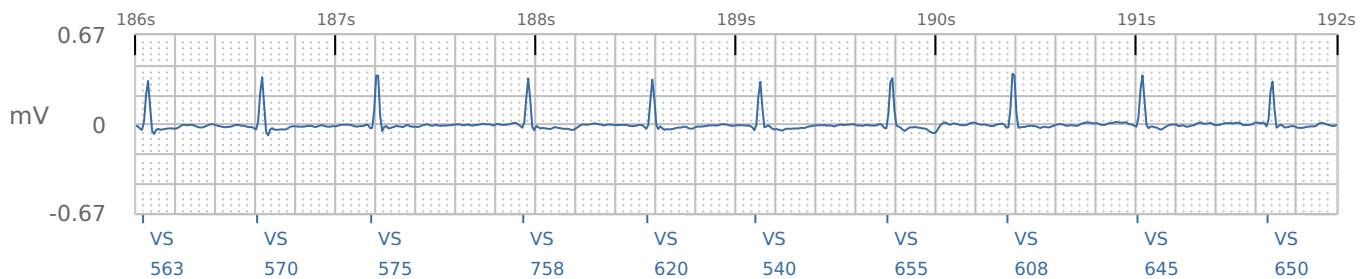


Comments & Interventions

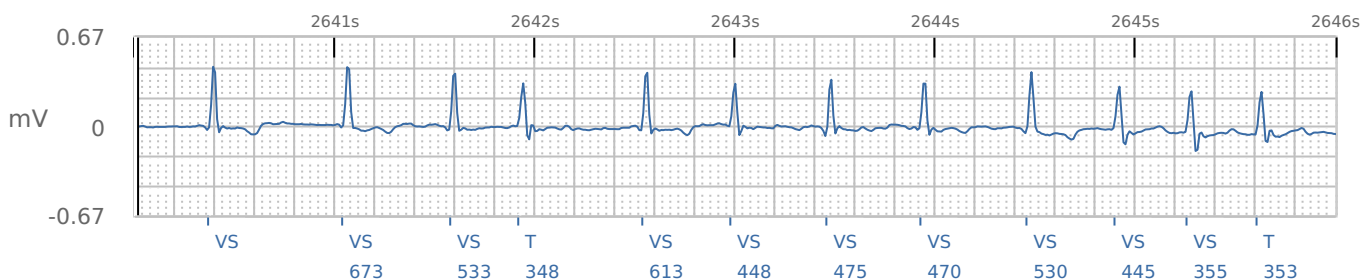
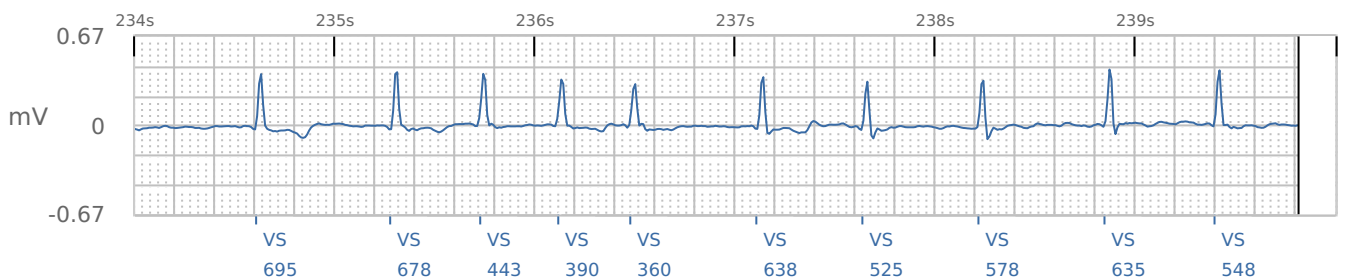
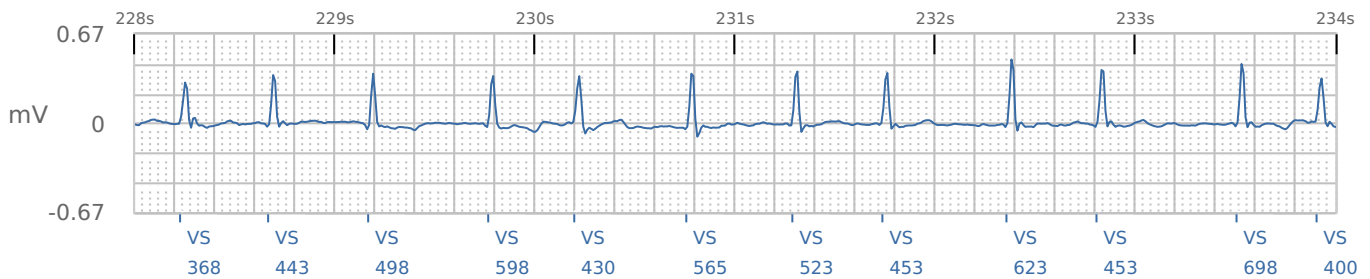
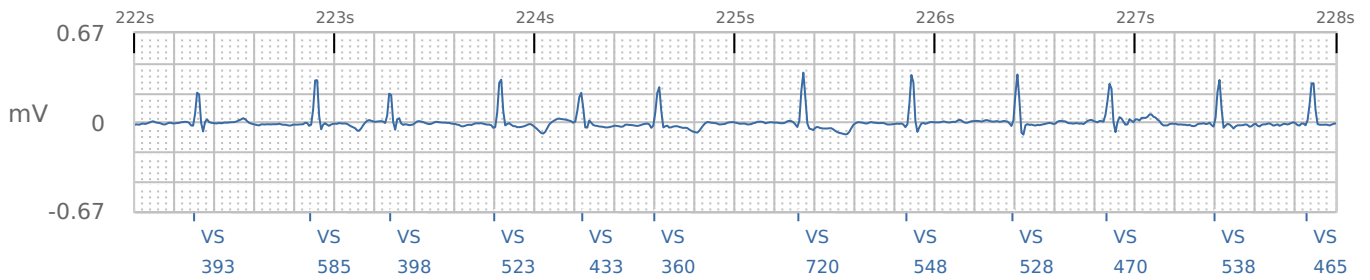
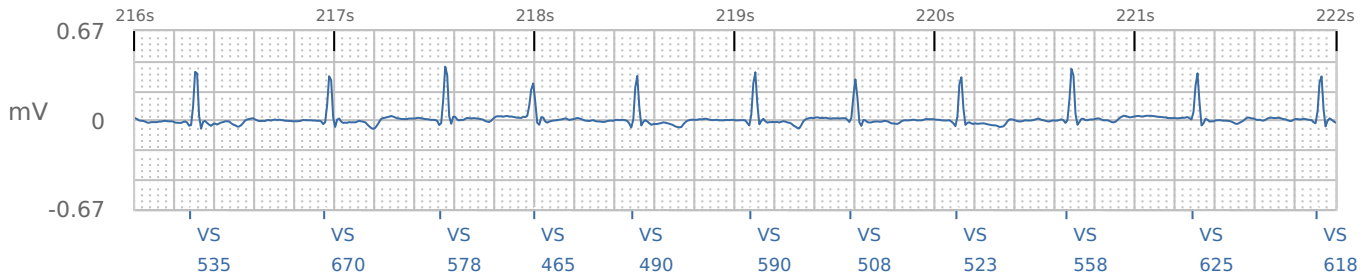
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Date

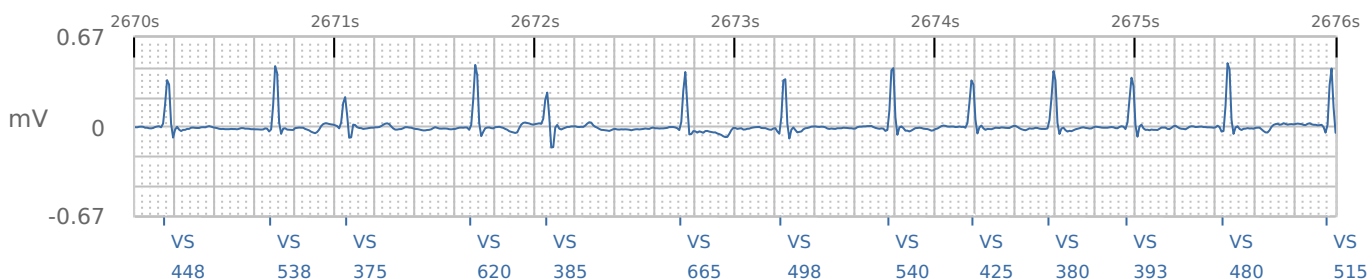
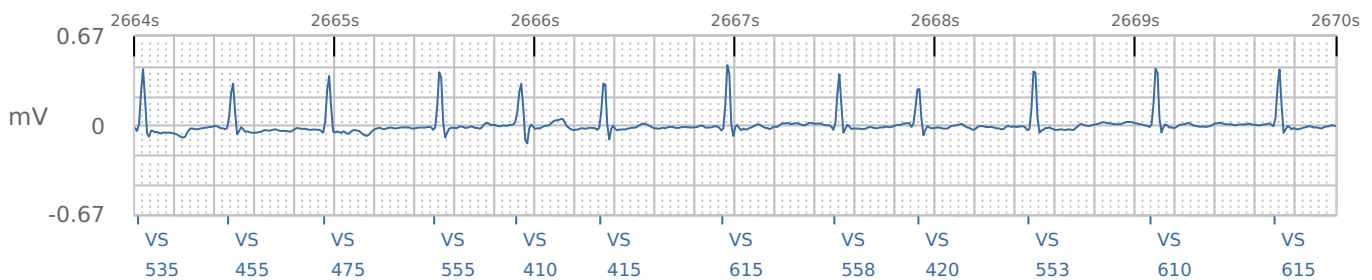
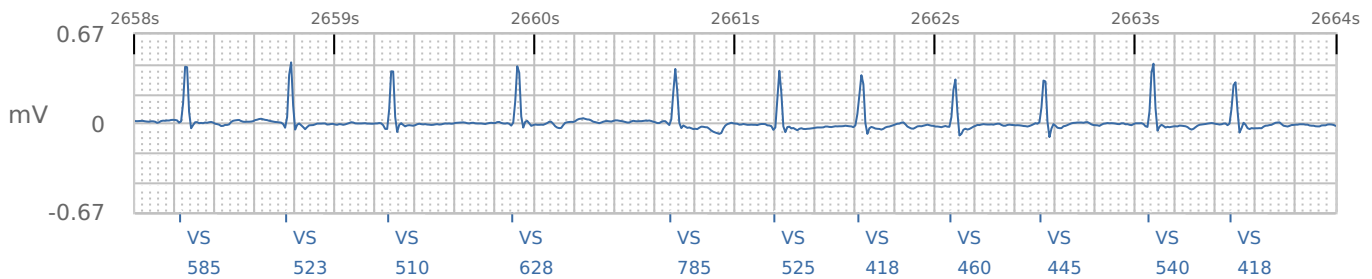
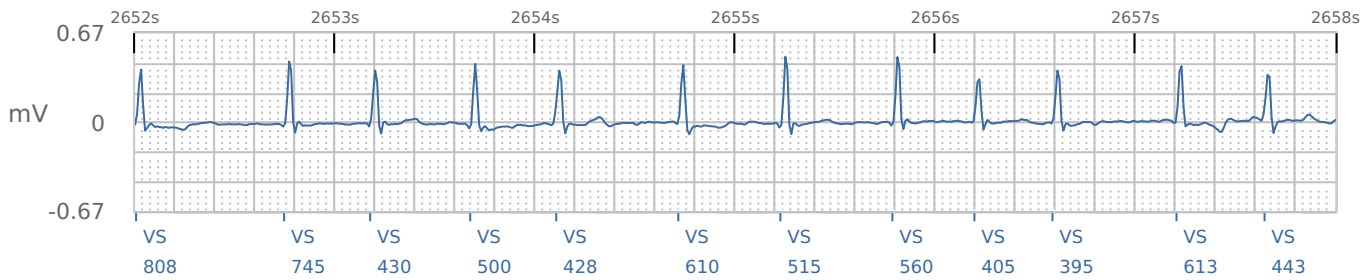
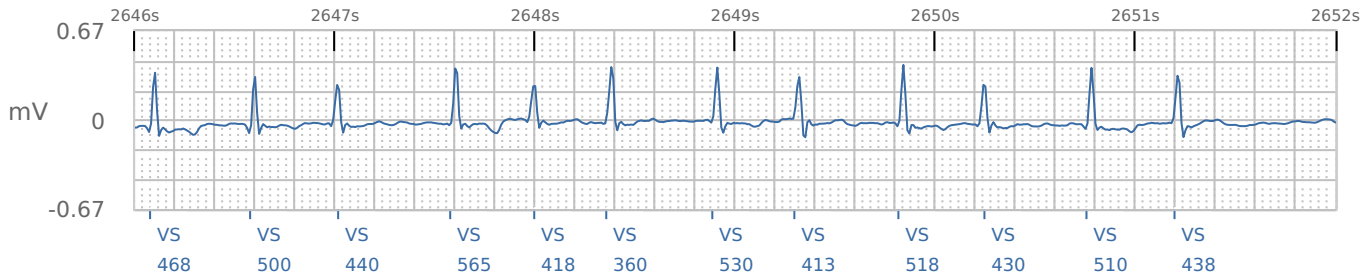
Monitoring: Syncope



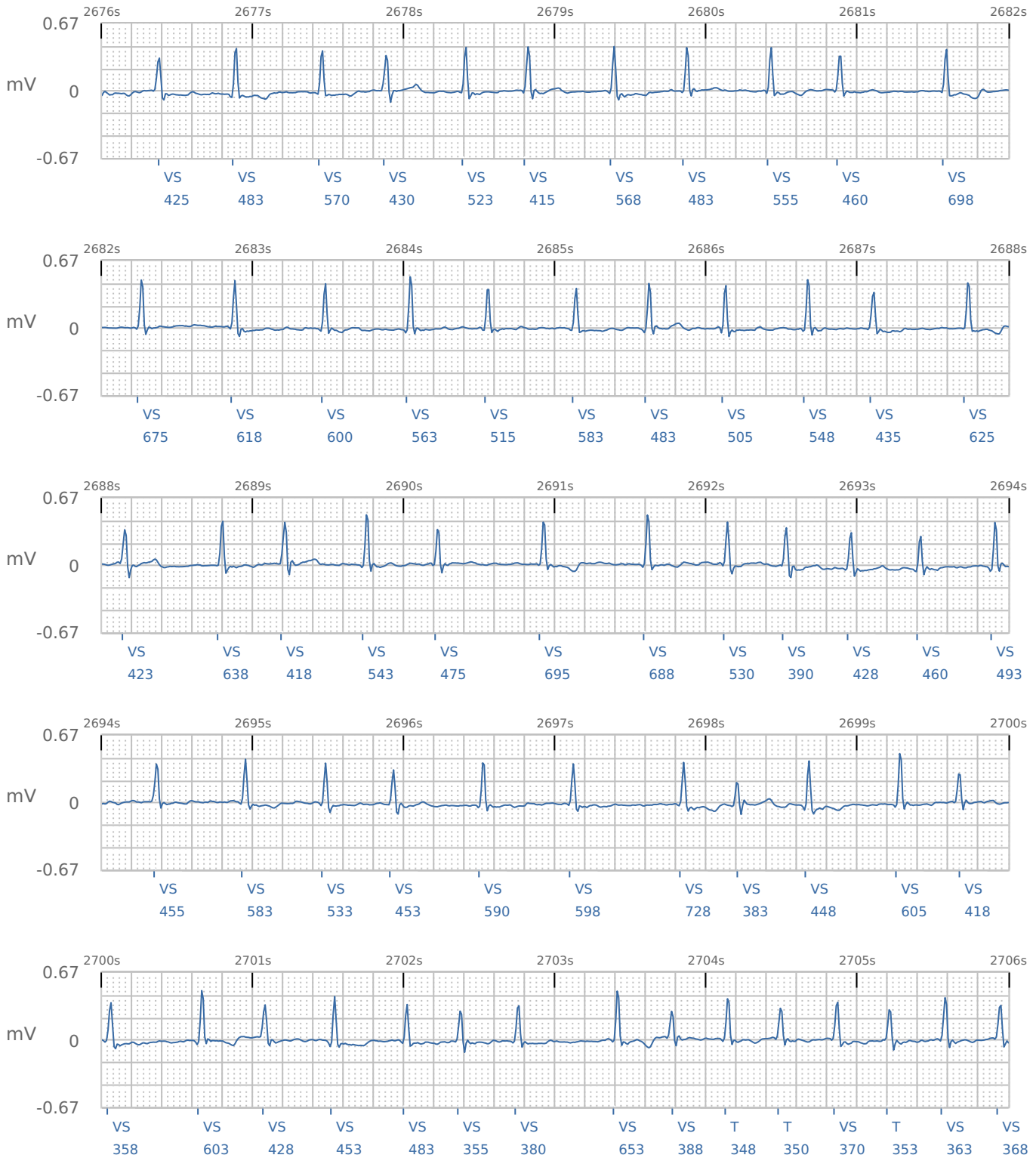
Monitoring: Syncope



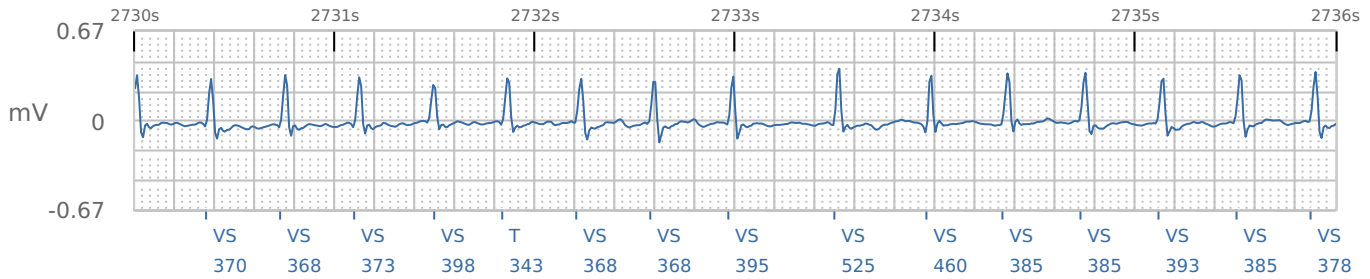
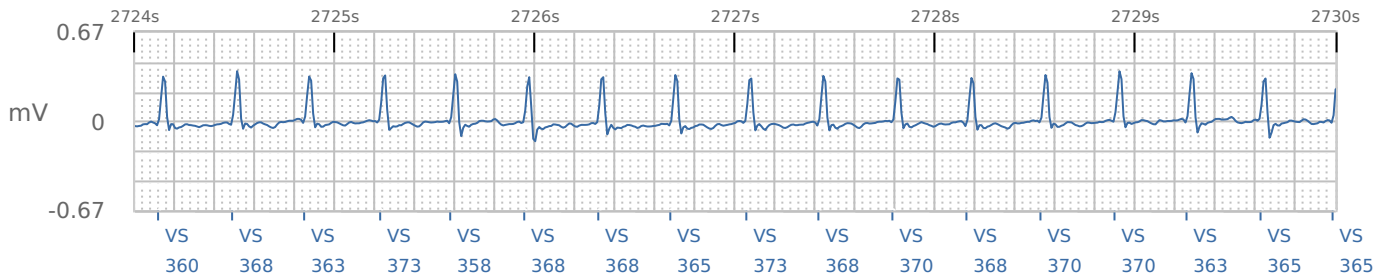
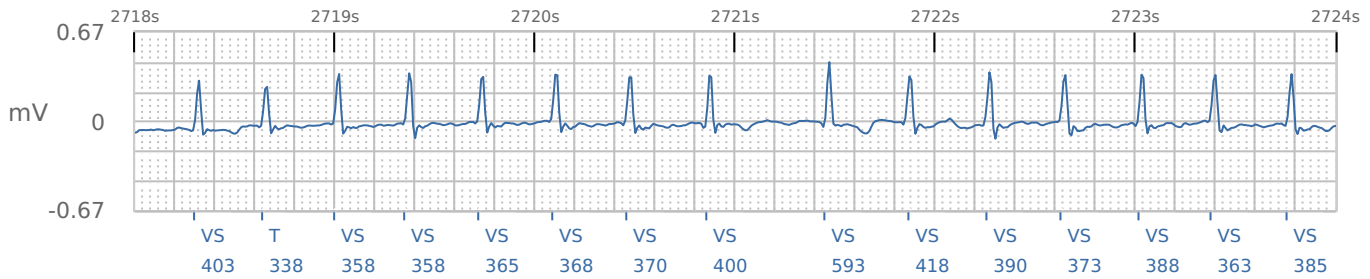
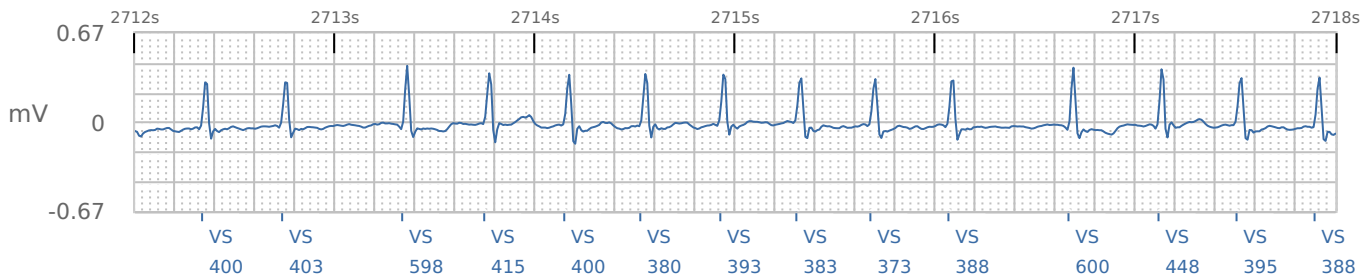
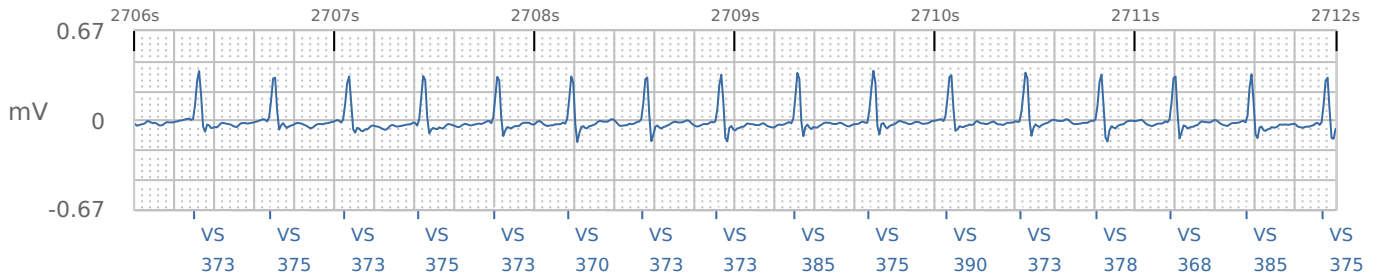
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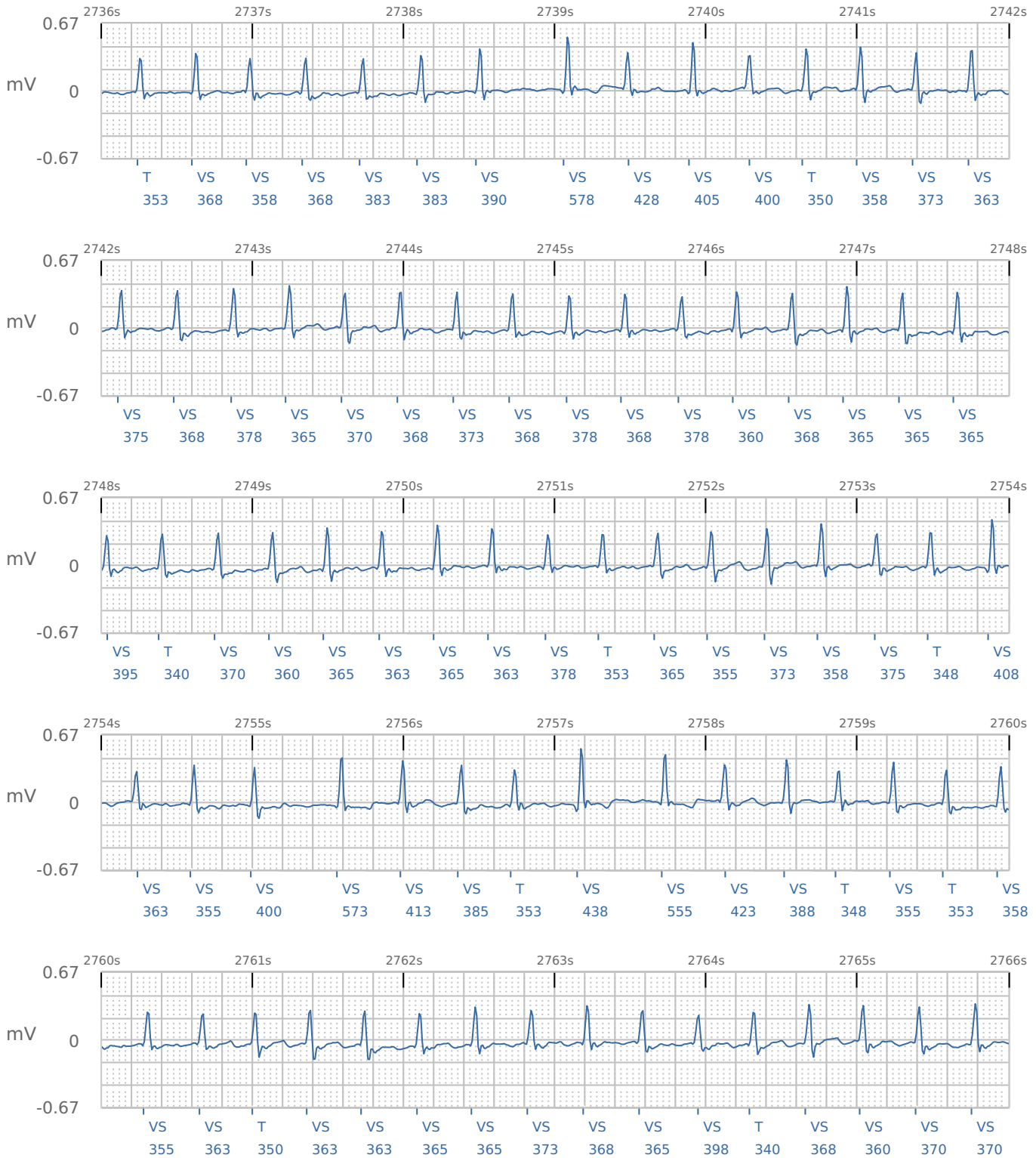
Monitoring: Syncope



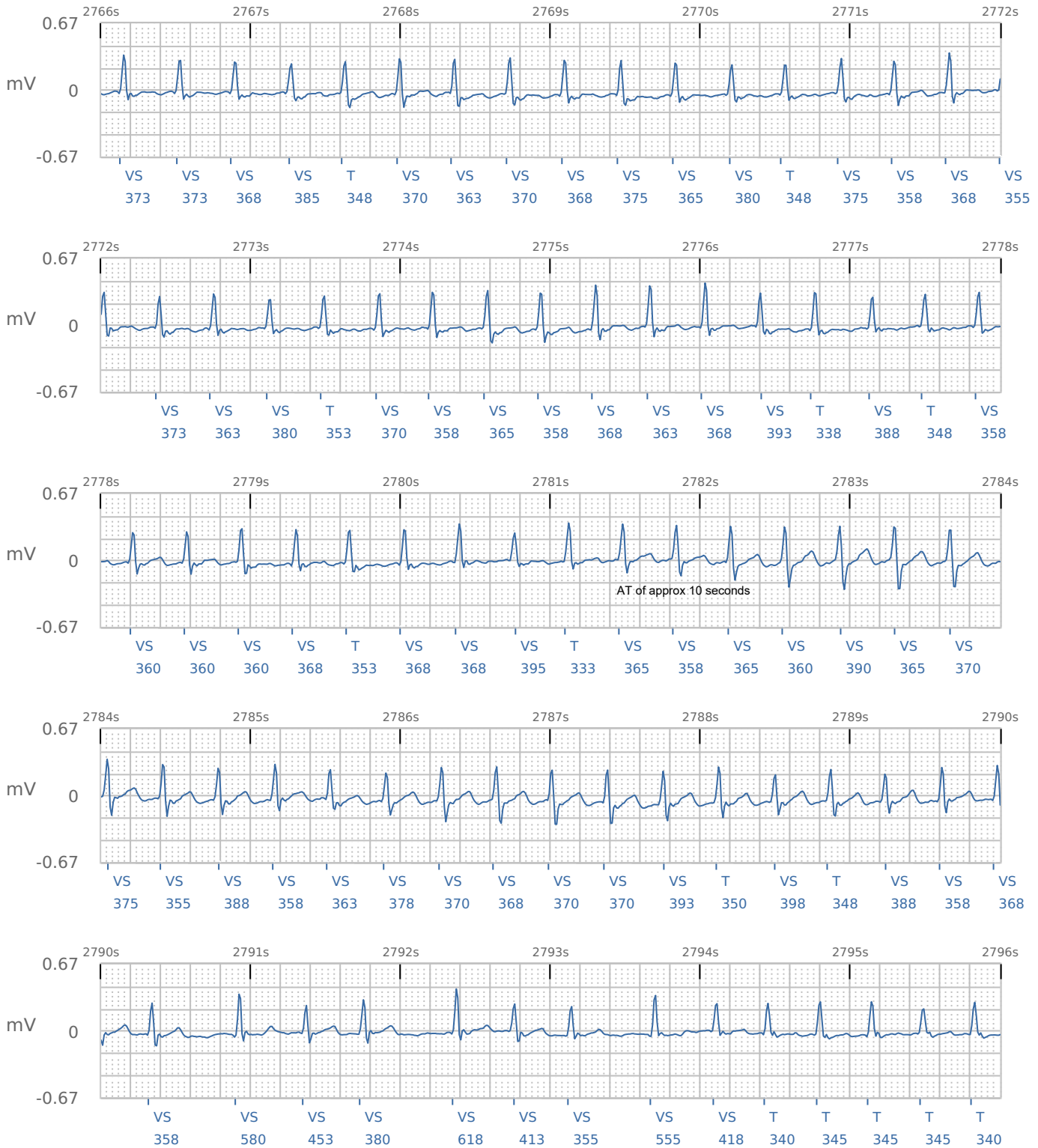
Monitoring: Syncope



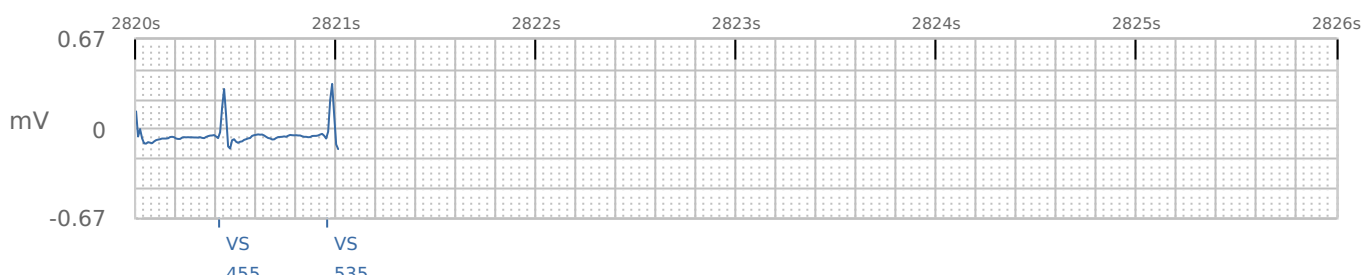
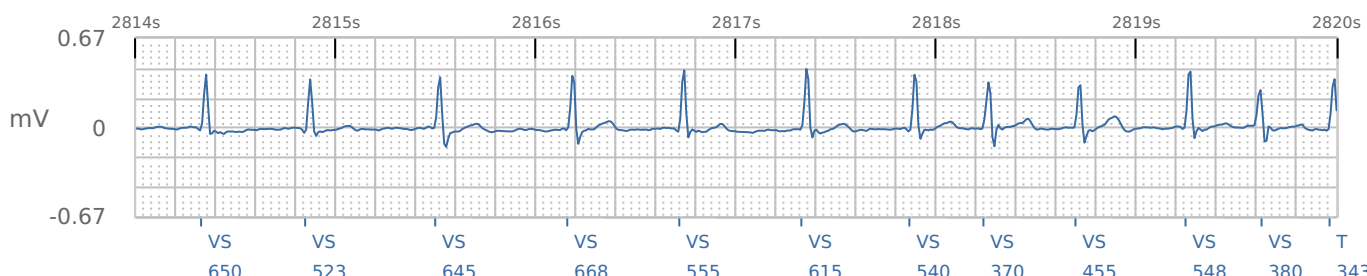
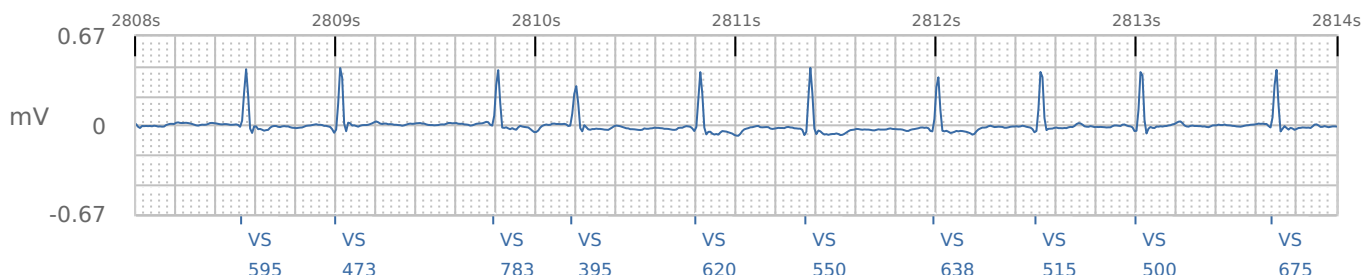
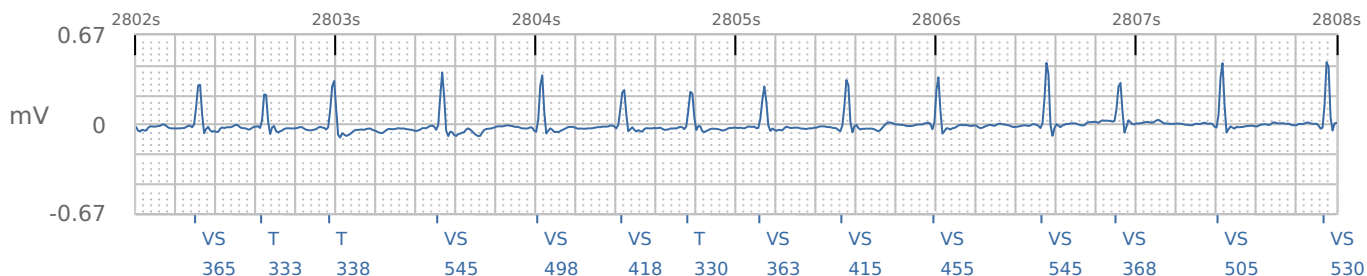
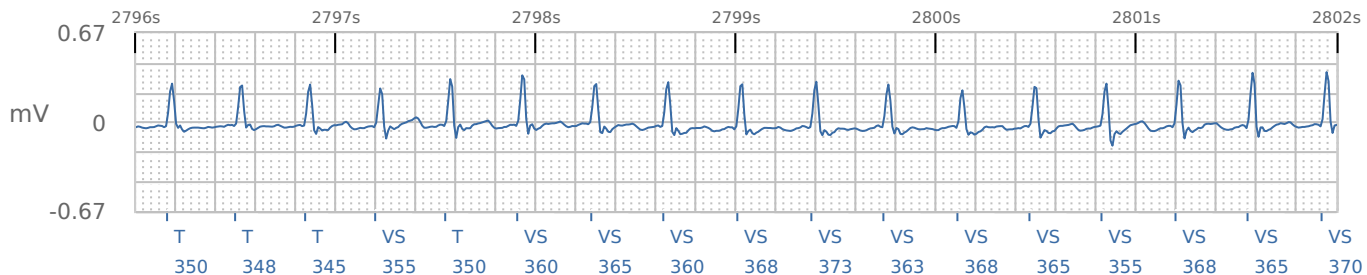
Monitoring: Syncope



Monitoring: Syncope



Monitoring: Syncope



End AF

DETAILS:

Two AF episodes showing Atrial Flutter with conversions to normal sinus rhythm

- Atrial flutter of 34-minute duration with an average ventricular rate of 86 bpm.
- The first conversion to NSR occurs between 239 seconds and 2040 seconds (report page 3), during a period that isn't stored in the S-ECG per storage guidelines below.
 - For S-ECG storage of an AF episode that's ≥ 2 minutes: each AF event contains 3 minutes of intervals before the start, 1 minute of annotated S-ECG data after the start, and up to 3 minutes of annotated S-ECG at the end.
- Atrial flutter begins again around 2115 seconds (report page 6).
- The conversion to NSR is visible at 2138 seconds (report page 7).
- AF settings were programmed to nominal.

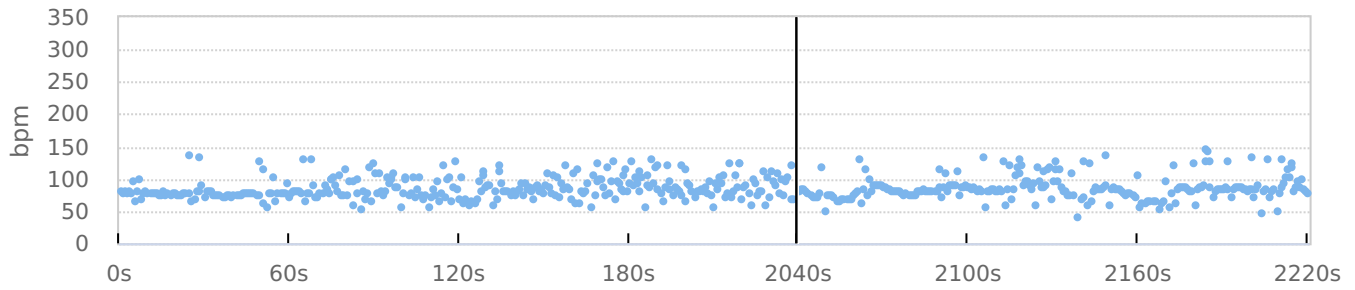


Reason For Monitoring
AF Management

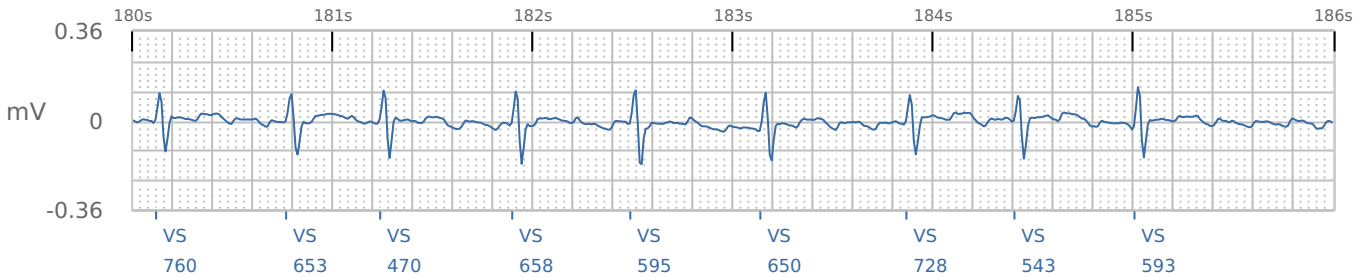
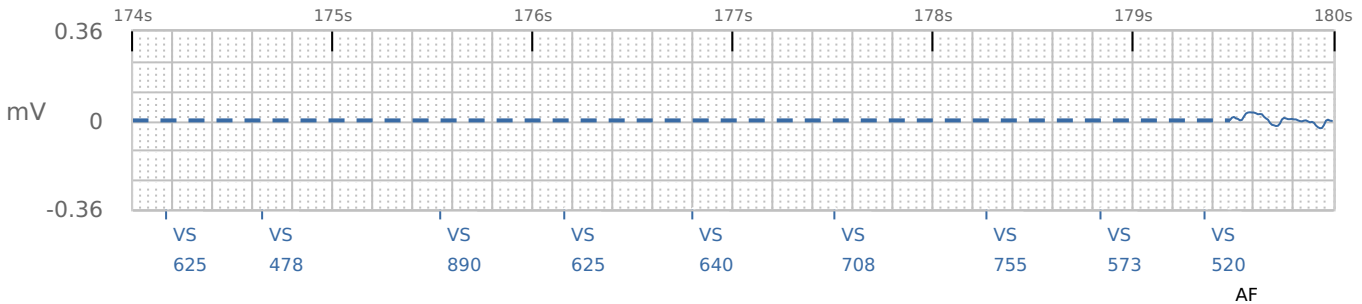
Clinical Context:
None

Event	Description	Date/Time	Duration	Rate	Assessment
AF-6	AF	Dec 04, 2020 05:10 EST	34 m 00 s	Avg 86 bpm Max 125 bpm	Appropriate

AF Settings
 Response Balanced
 Duration 10 min
 Morphology Assessment On



S-ECG displayed at 25mm per second



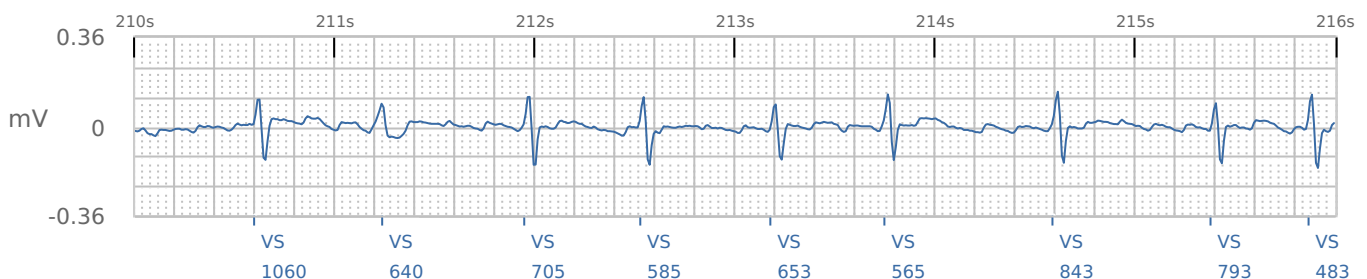
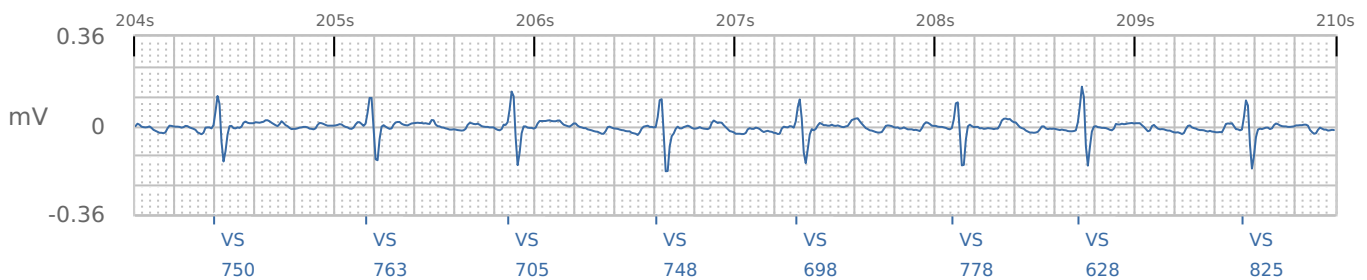
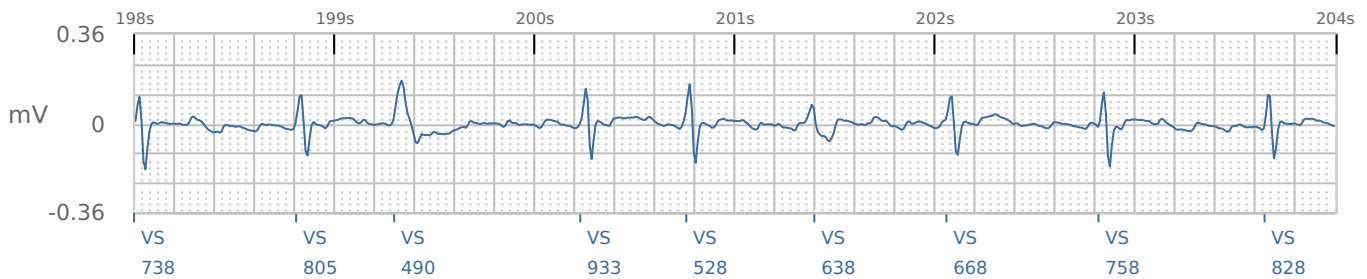
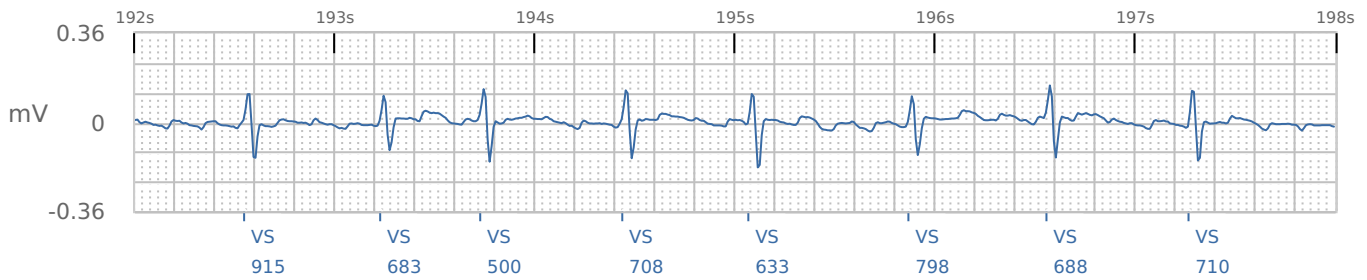
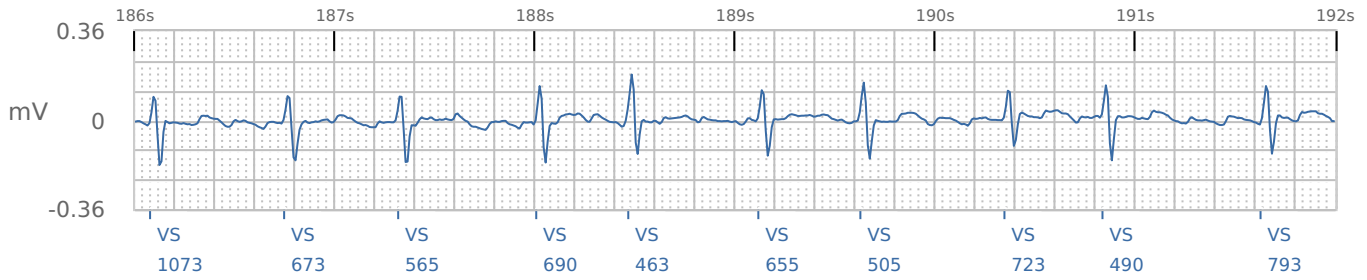
Comments & Interventions

Signature

Date

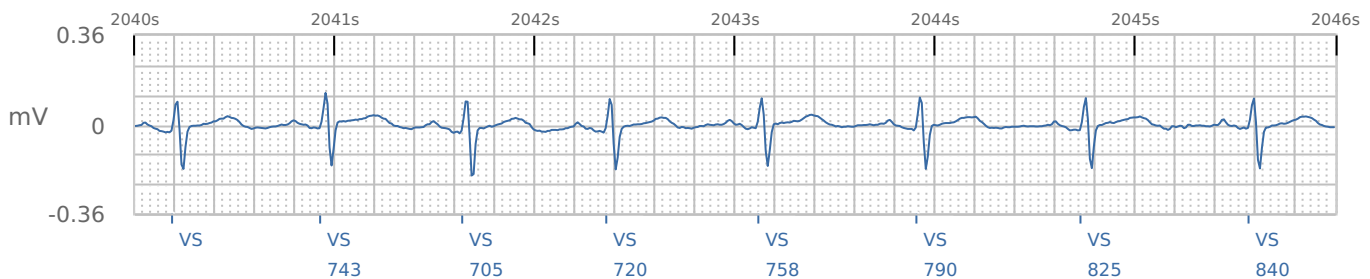
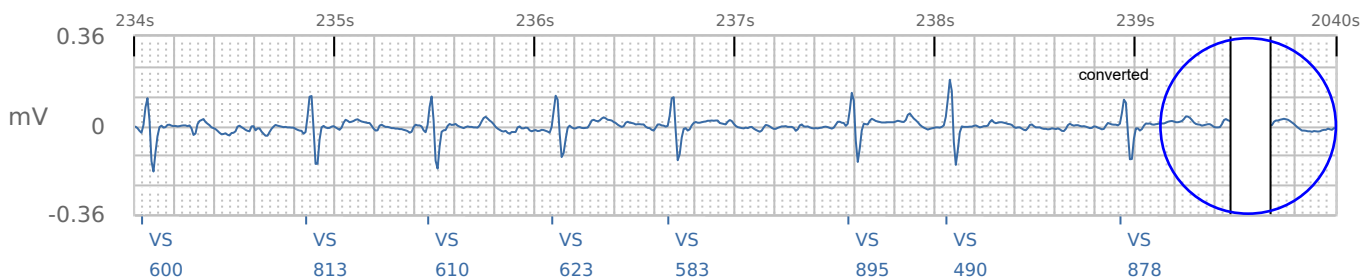
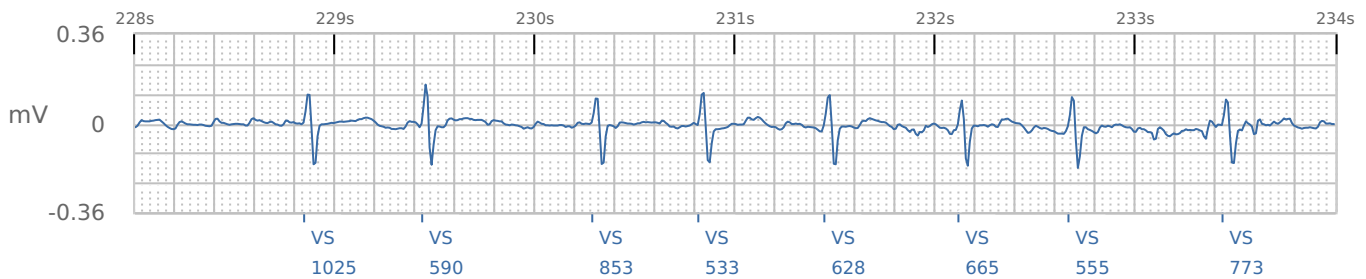
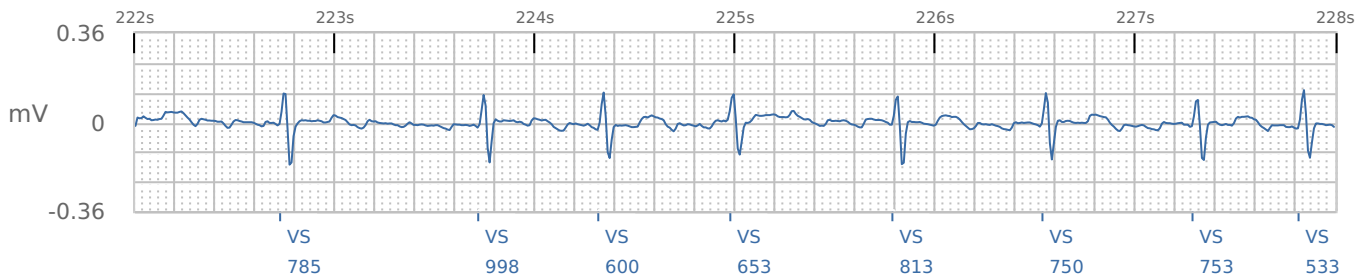
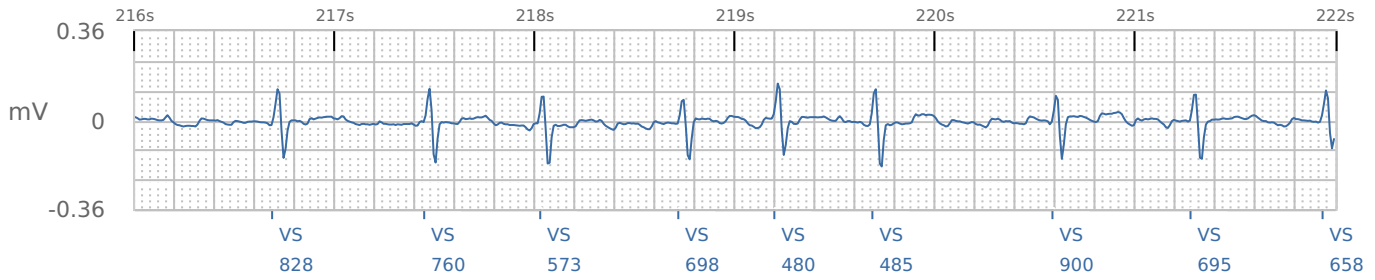
ID:

Monitoring: AF Management



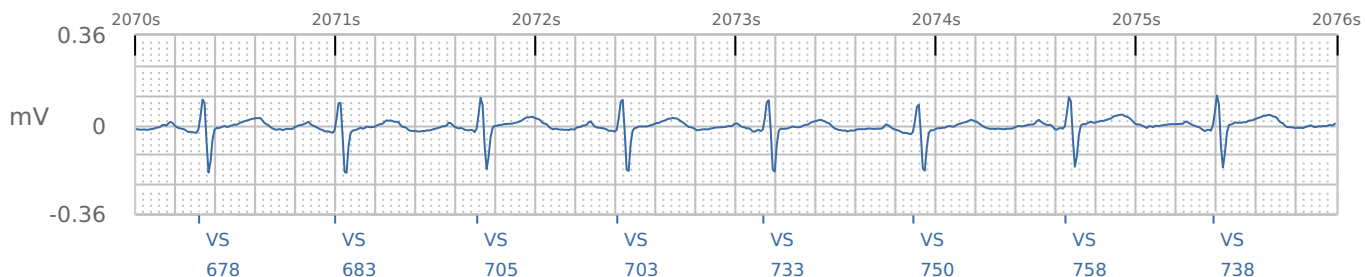
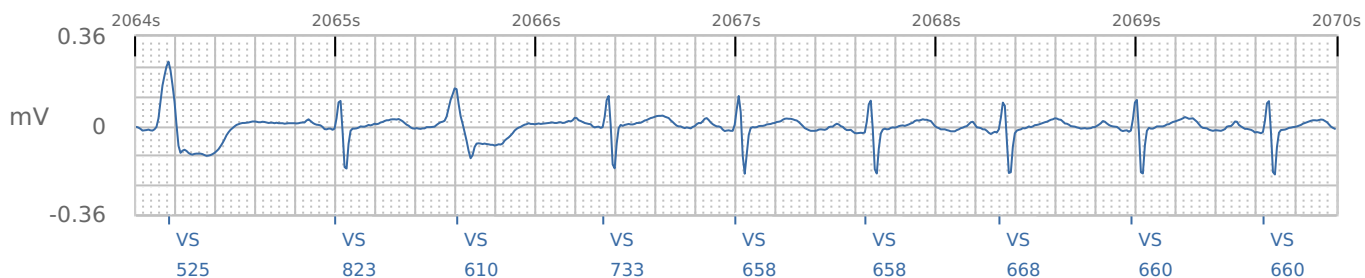
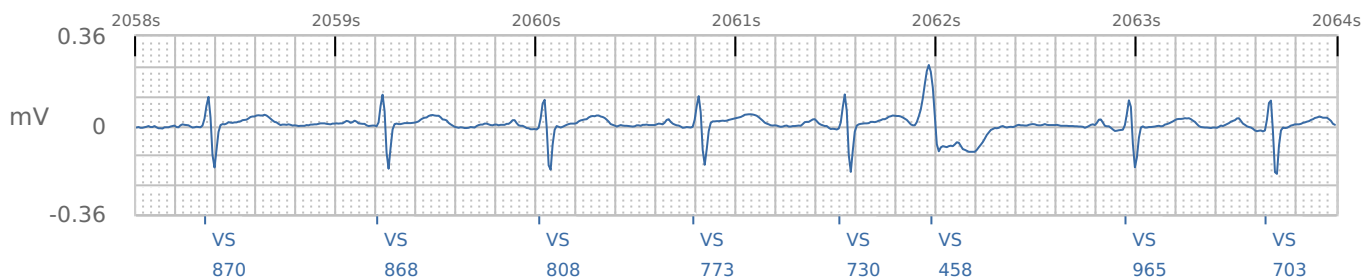
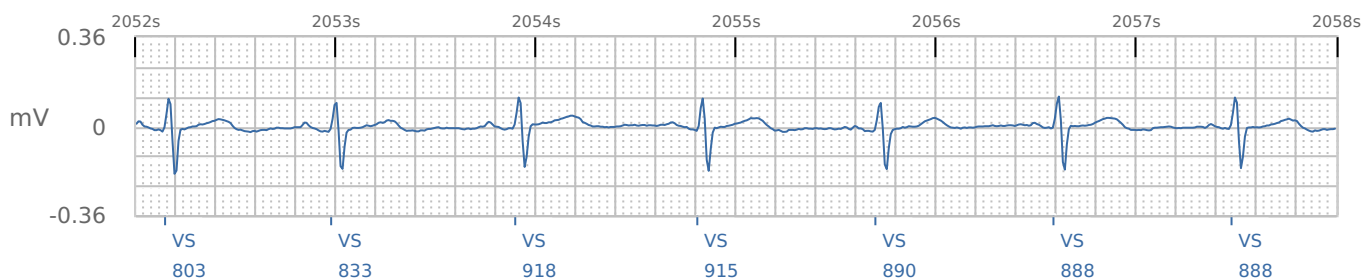
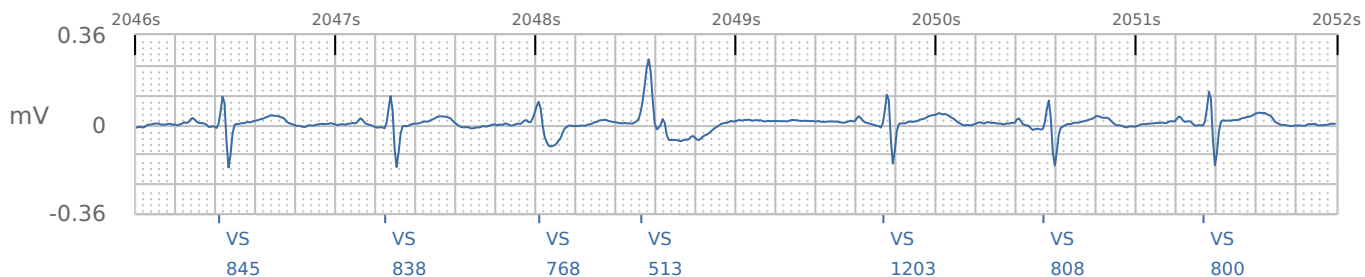
ID:

Monitoring: AF Management



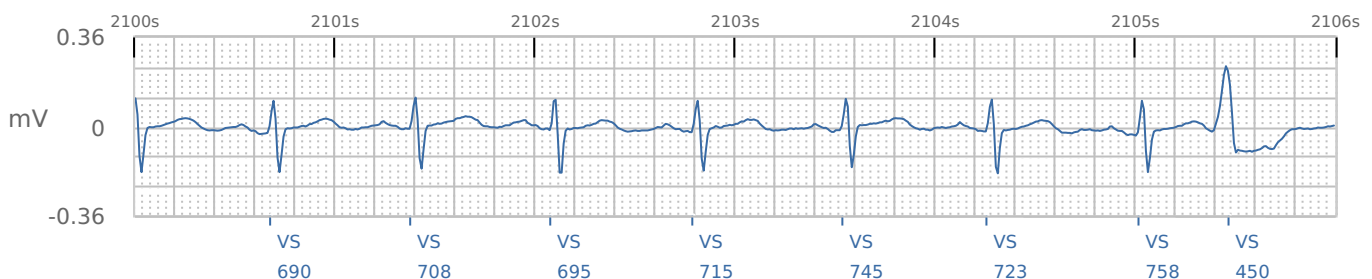
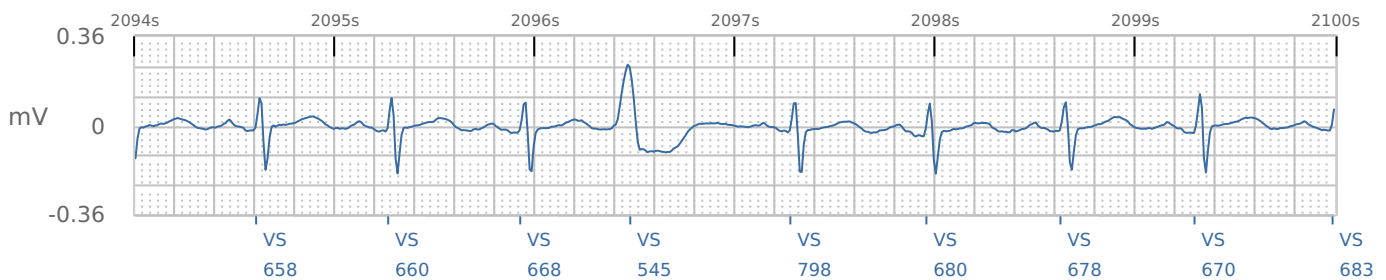
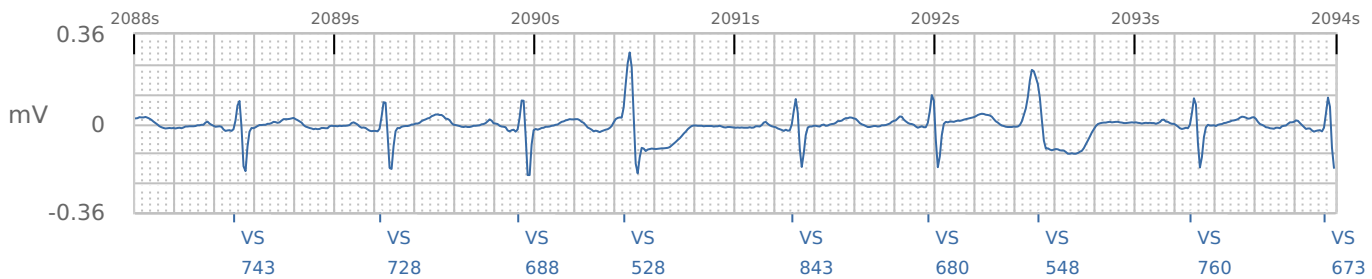
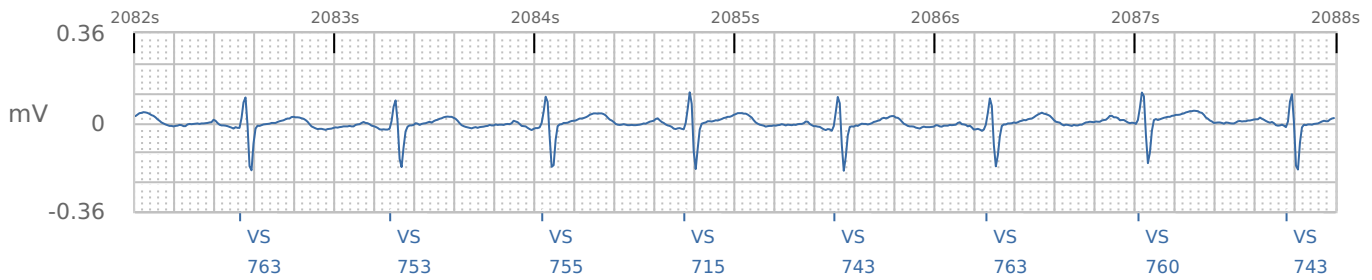
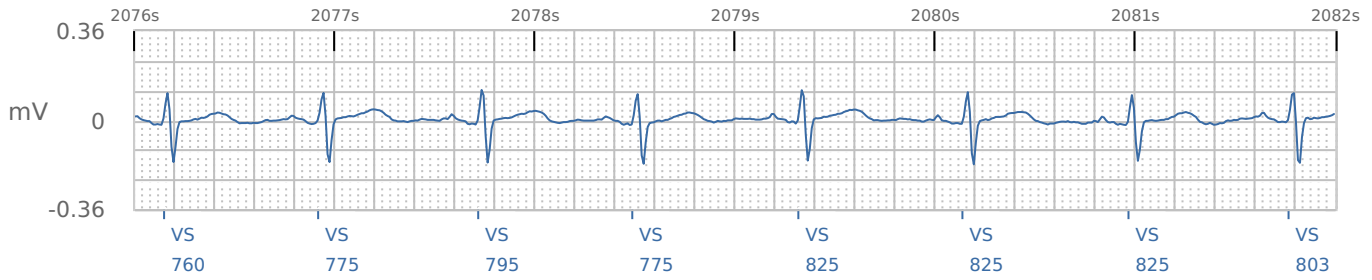
ID:

Monitoring: AF Management



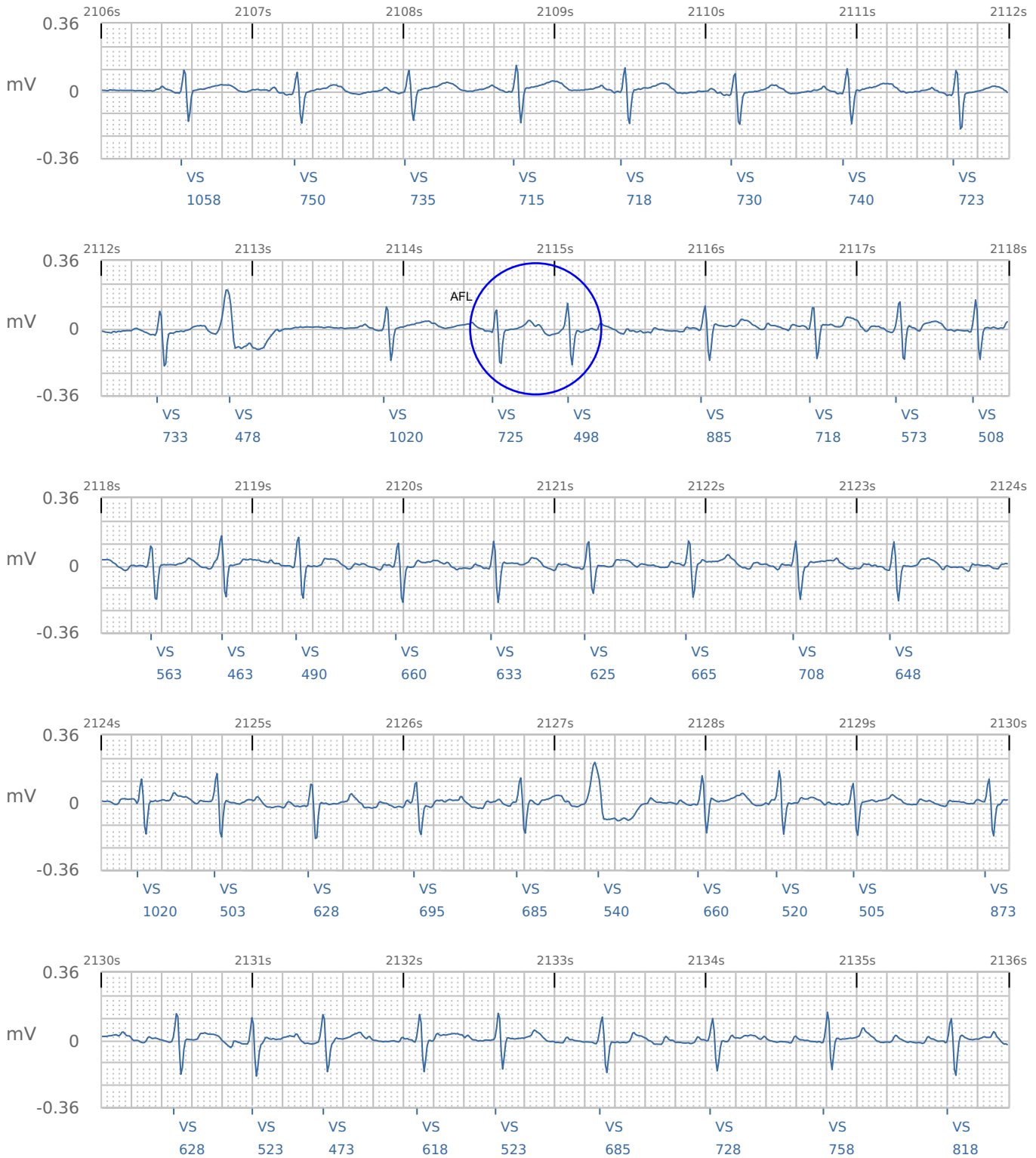
ID:

Monitoring: AF Management



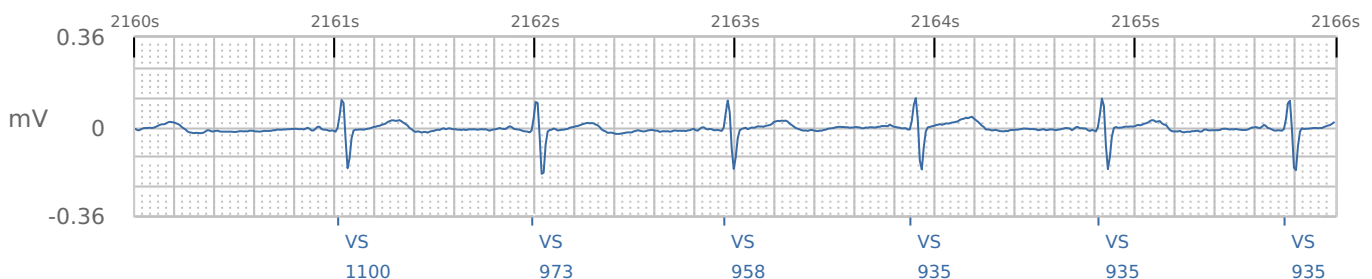
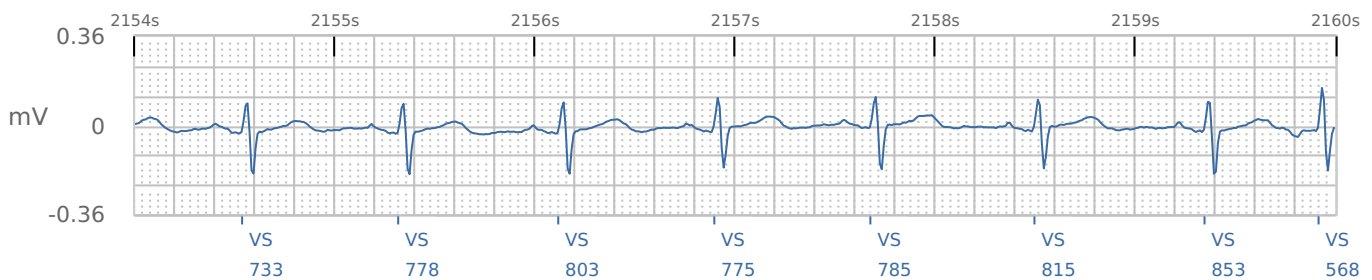
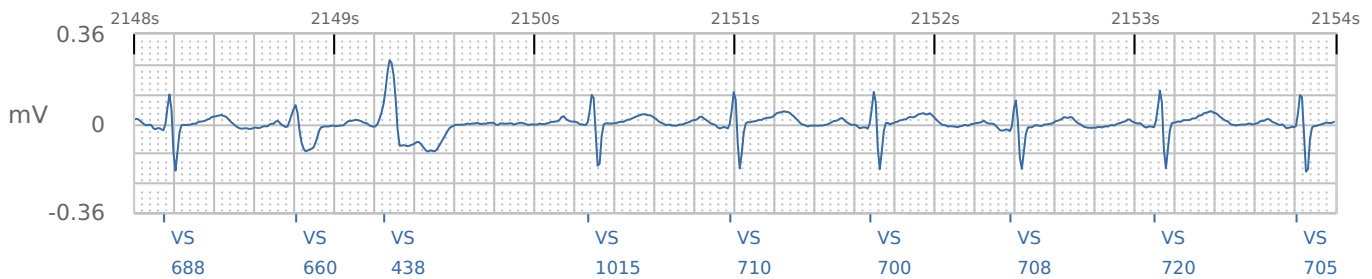
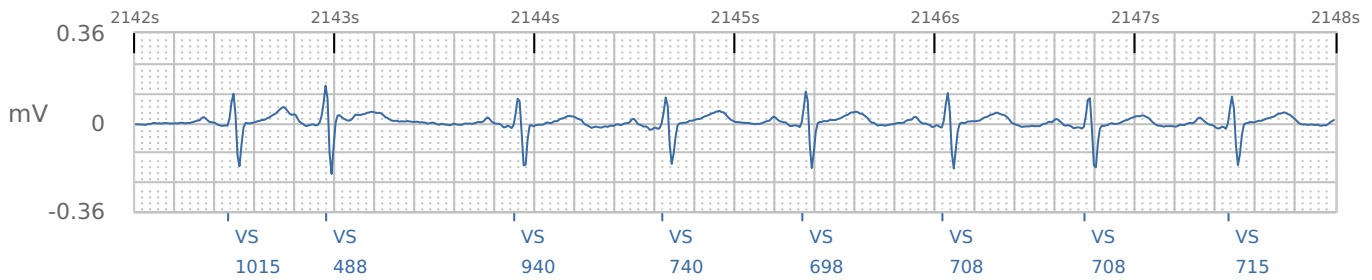
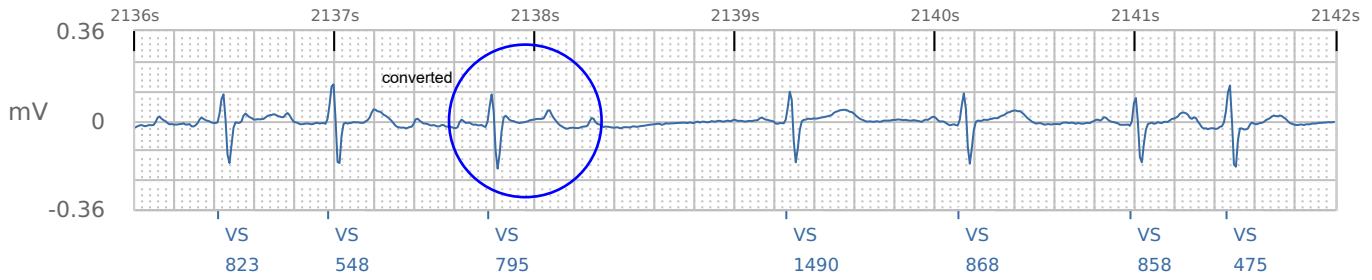
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Monitoring: AF Management



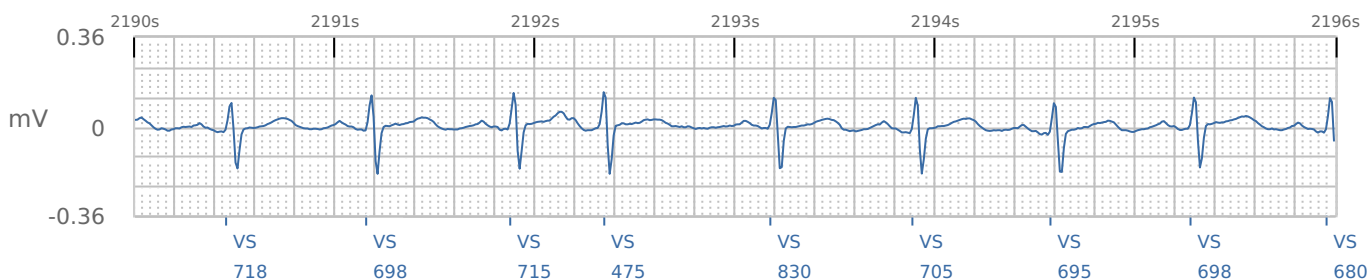
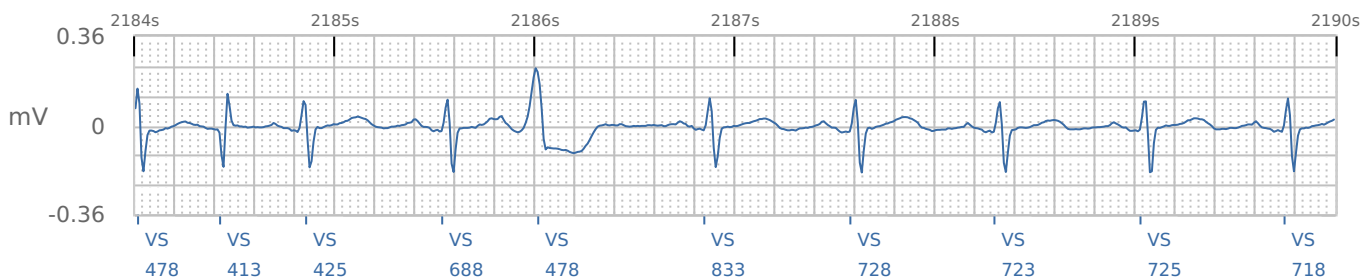
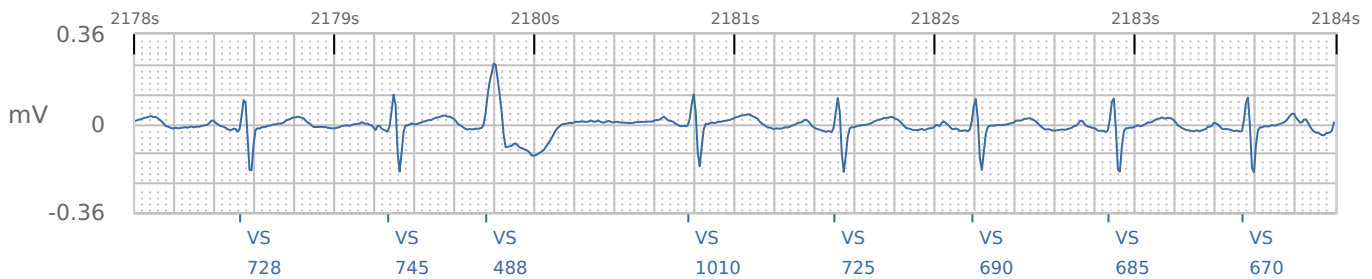
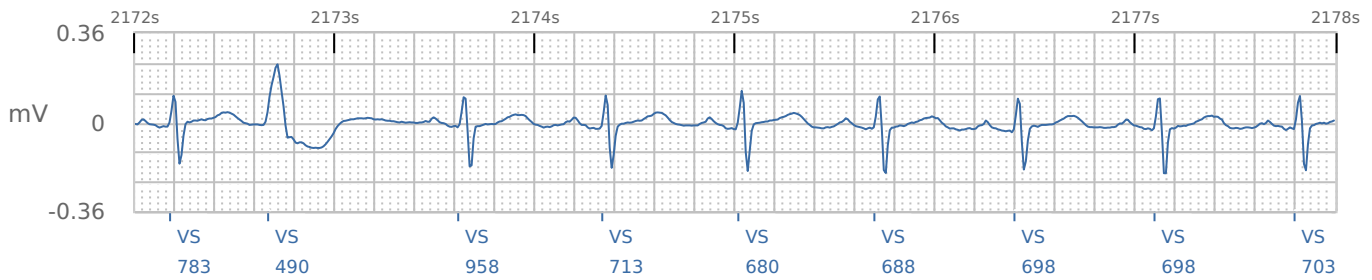
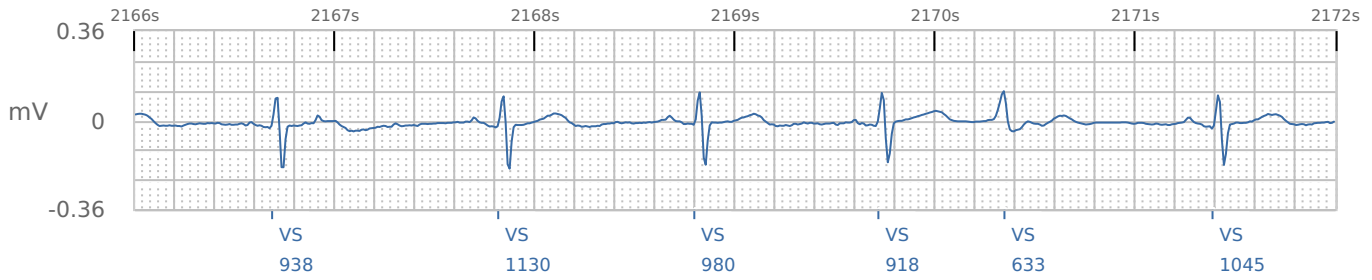
ID:

Monitoring: AF Management



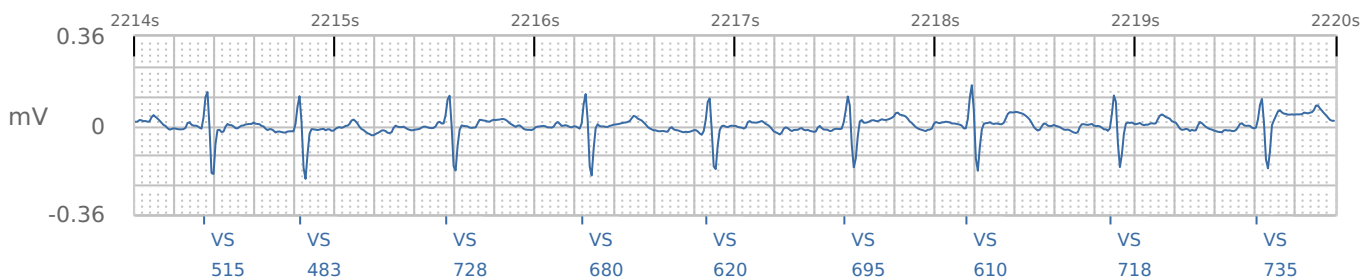
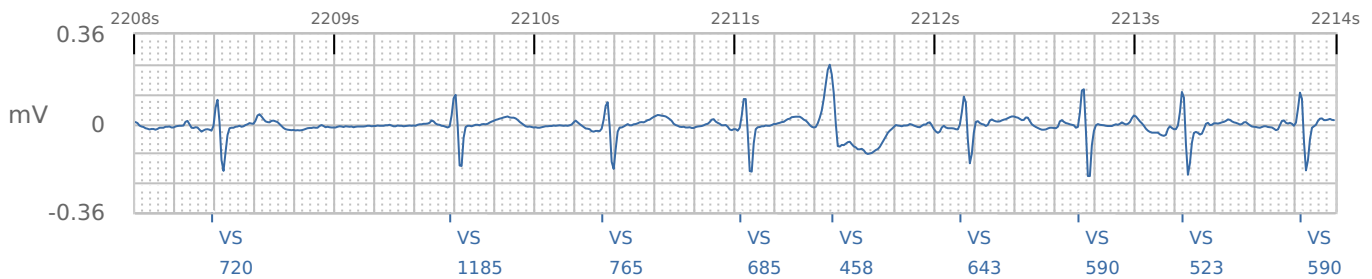
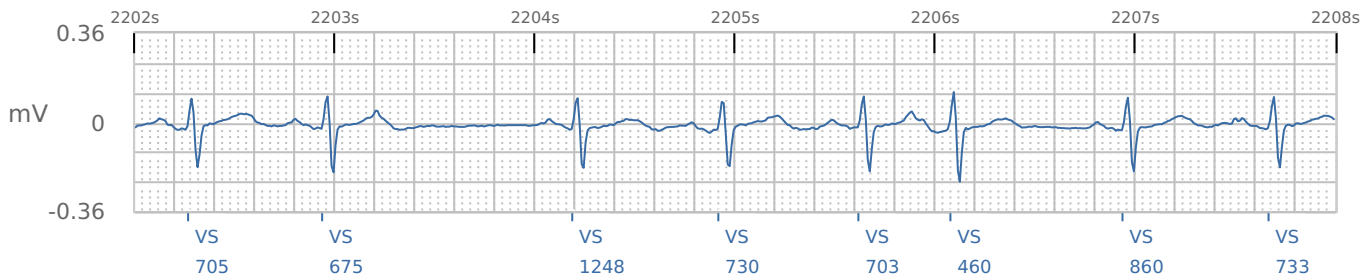
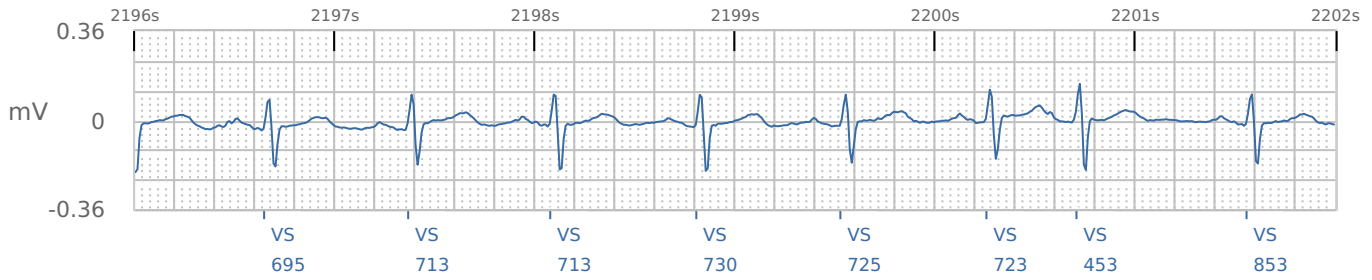
ID:

Monitoring: AF Management

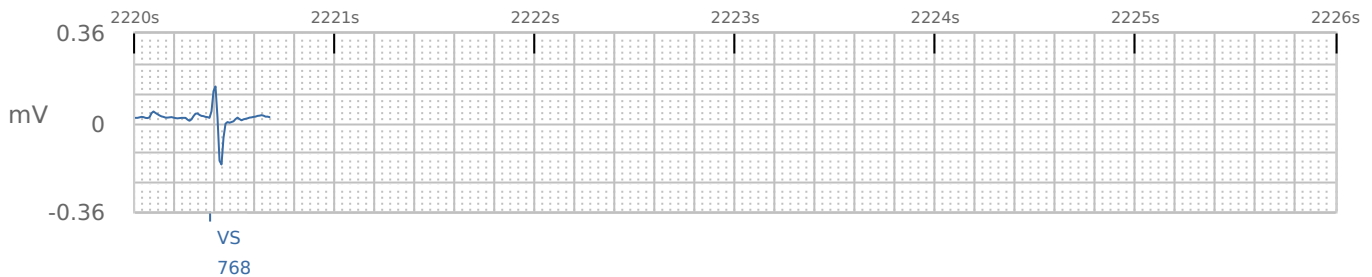


ID:

Monitoring: AF Management



End AF



PATIENT MONITORED FOR: Syncope

DETAILS:

High degree AV block detected

- At 7:04AM, a 3.7 second pause was detected.
- P-waves can be seen during AV block prior to the pause.
- P-waves are visible during the 3.7 second pause (report page 2).
- Ventricular sensing at 66 bpm. Bradycardia noted at 4 second mark with a heart rate of 32 bpm (report page 1).
- It may be of interest to see if the patient is on an antiarrhythmic medication that could put them at risk for pause.
- Pause settings were programmed to nominal.

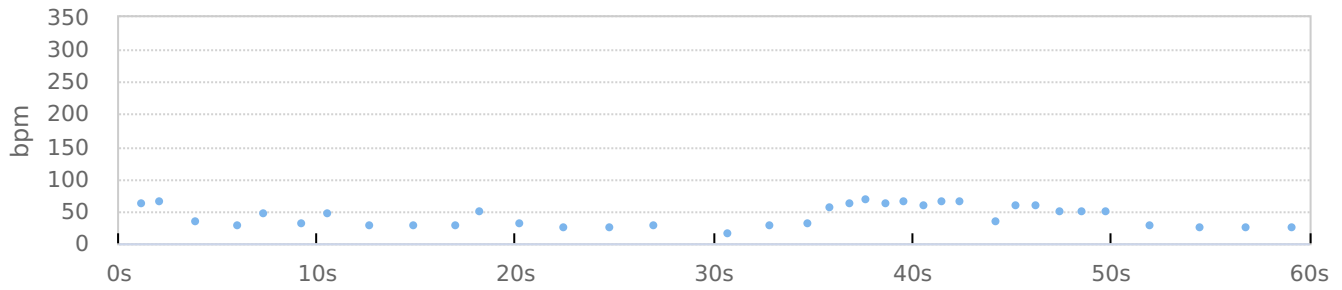


Reason For Monitoring
Syncope

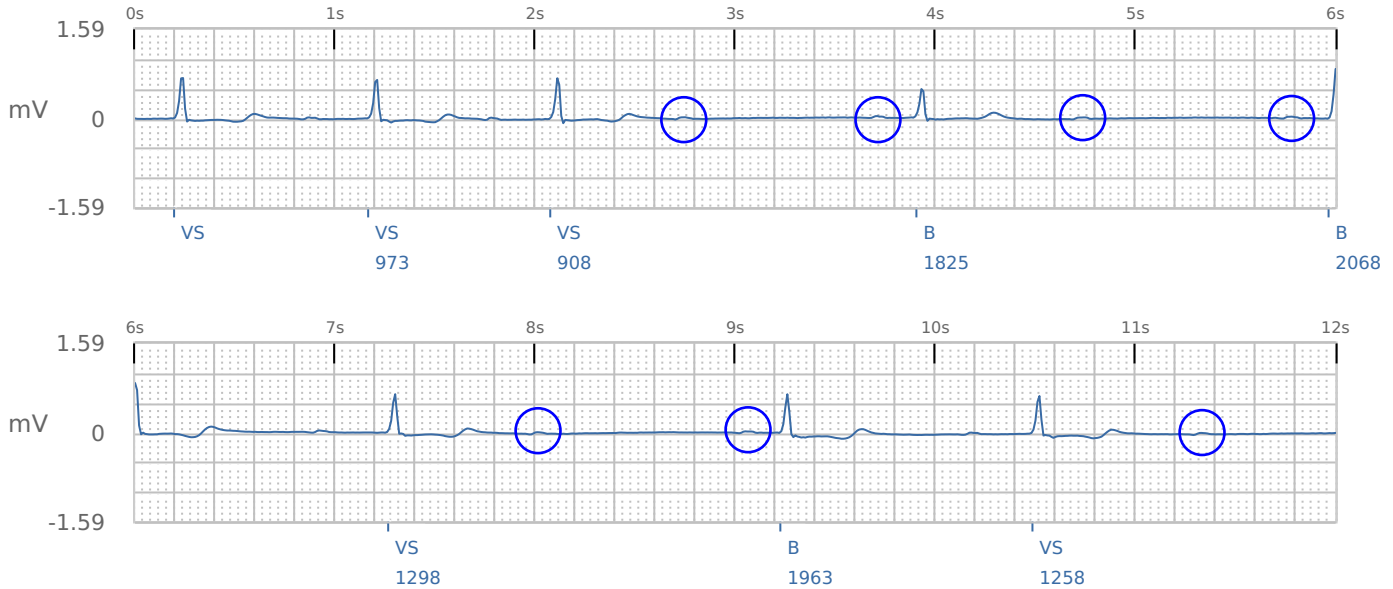
On OAC: No
On Antiarrhythmic: No
Sleep Apnea: No

Event	Description	Date/Time	Duration	Rate	Assessment
P-6	Pause	Oct 08, 2020 07:04 CDT	3.7 s	--	Appropriate

Pause Settings
Duration 3 s
Response More



S-ECG displayed at 25mm per second

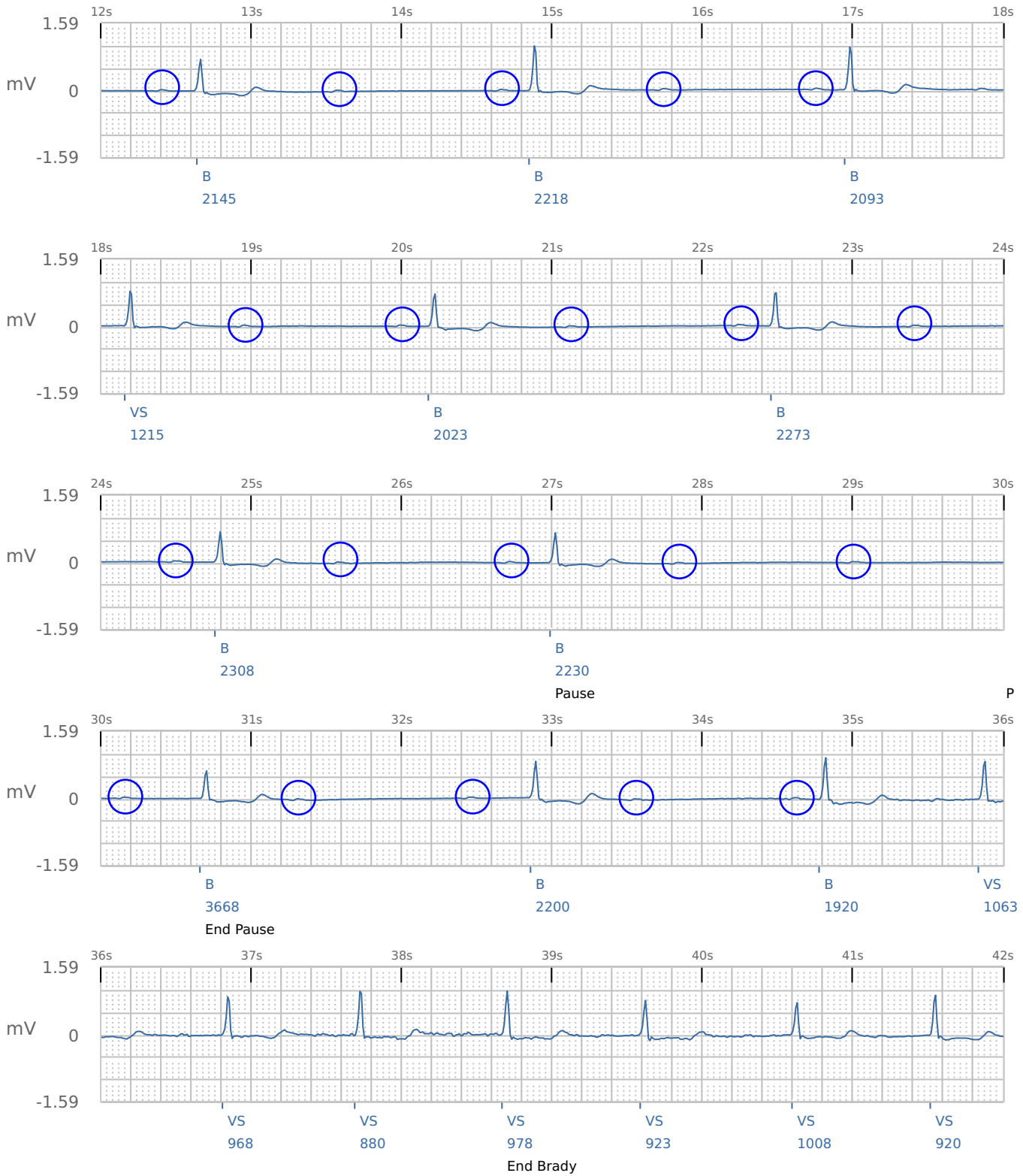


Comments & Interventions

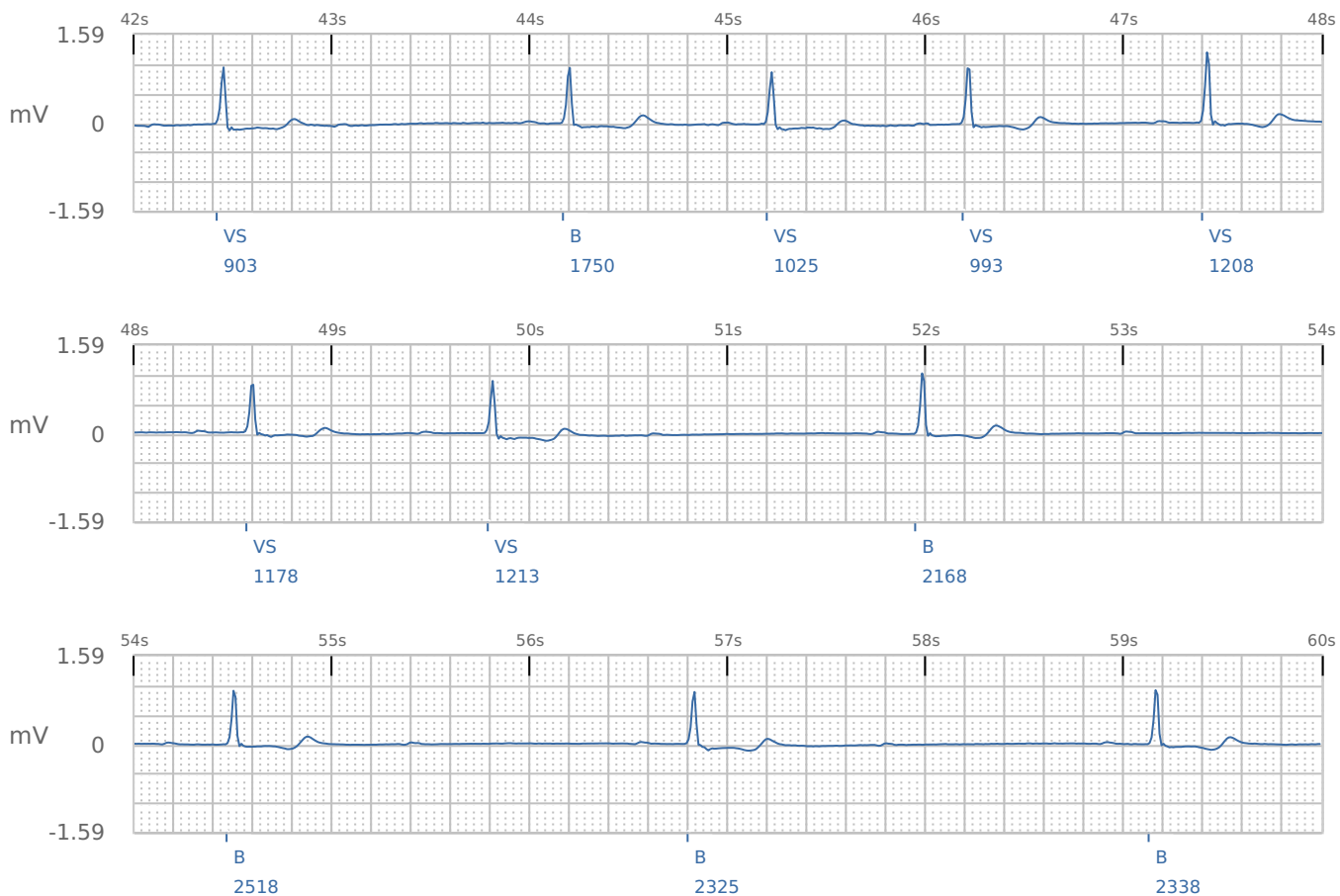
Signature

Date

Monitoring: Syncope



Monitoring: Syncope



PATIENT MONITORED FOR: Cryptogenic Stroke

DETAILS:

4.8 second pause supported by the rate plot

- At 5:34AM, a 4.8 second pause was detected.
- In the rate plot, a heart rate drop is visible prior to and after the pause supporting a true pause.
- The beginning of the pause can be seen at 27 seconds and the end can be seen at 32 seconds, confirming the 4.8 second event duration (report page 2).
- Noise can be seen at the beginning of the report that was marked as noise per the VN marker.
- Pause settings were programmed to nominal.

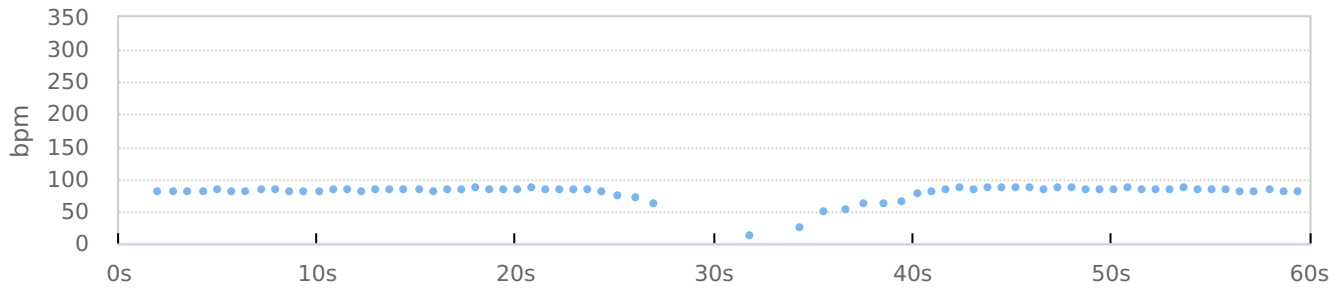


Reason For Monitoring
Cryptogenic Stroke

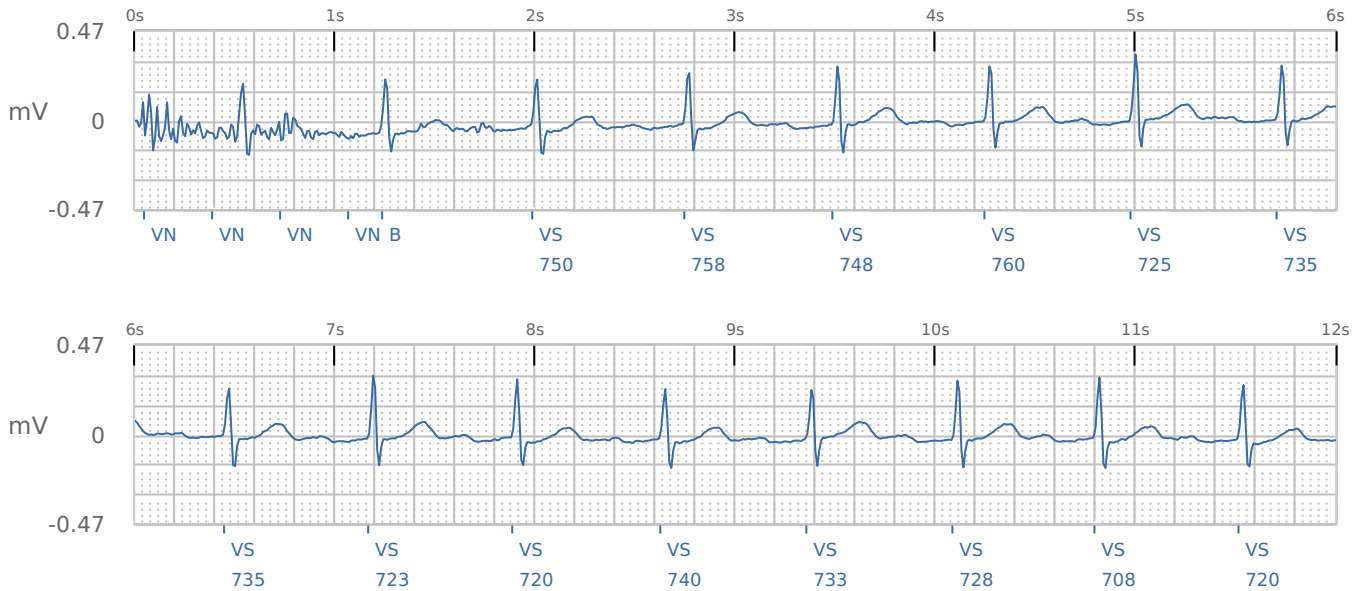
Clinical Context:
None

Event	Description	Date/Time	Duration	Rate	Assessment
P-1	Pause	Oct 03, 2020 05:34 CDT	4.8 s	--	Appropriate

Pause Settings
Duration 3 s
Response Less



S-ECG displayed at 25mm per second



Comments & Interventions

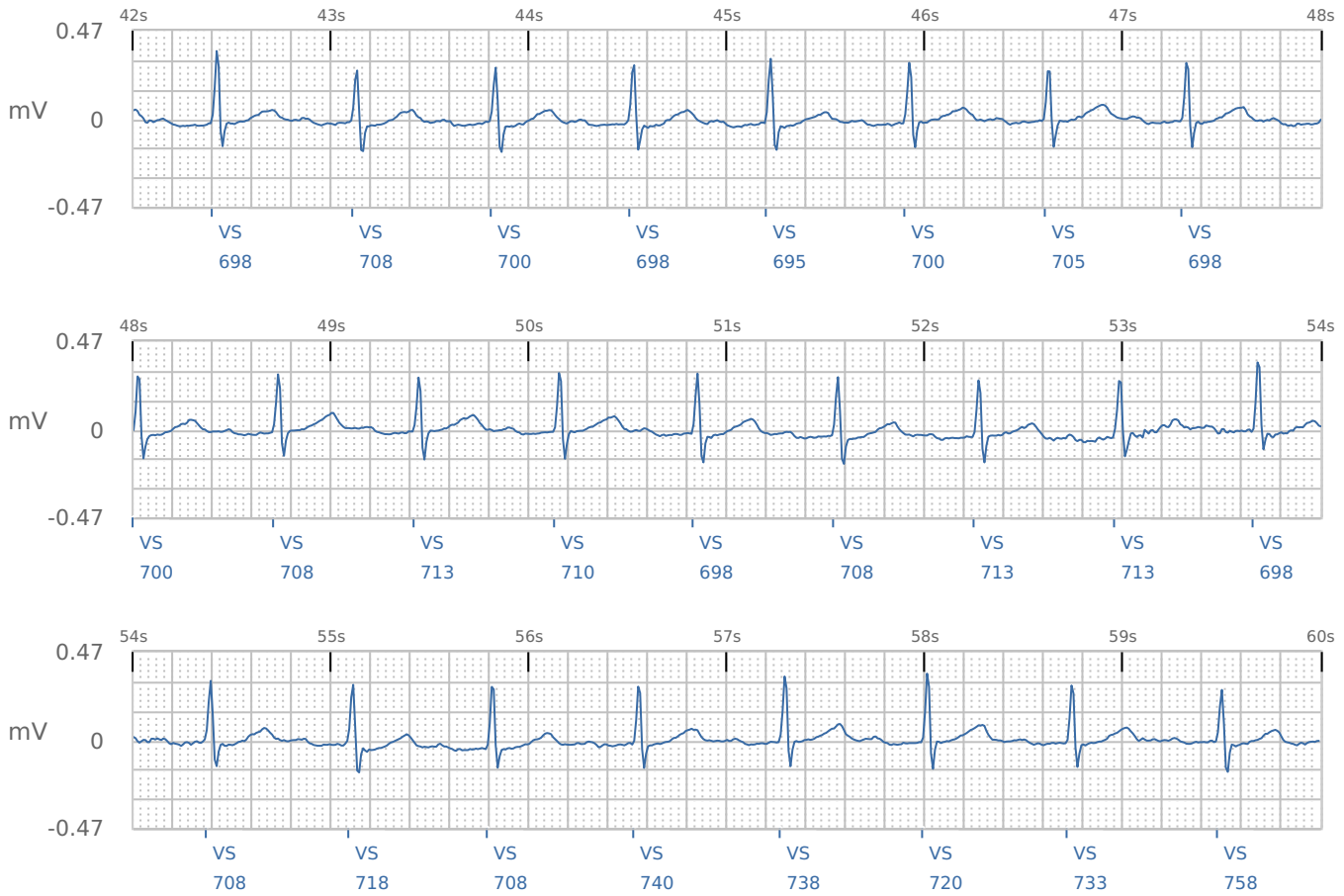
Signature

Date

Monitoring: Cryptogenic Stroke



Monitoring: Cryptogenic Stroke



PATIENT MONITORED FOR: Syncope

DETAILS:

8.8 second pause

- At 5:00AM, an 8.8 second pause was detected.
- The beginning of the pause can be seen at 27 seconds (page 2).
- Pause settings were programmed to nominal.

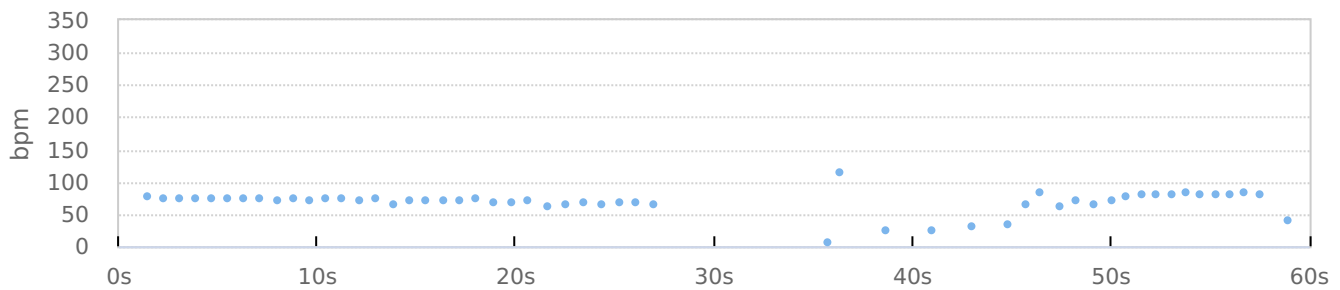


Reason For Monitoring
Syncope

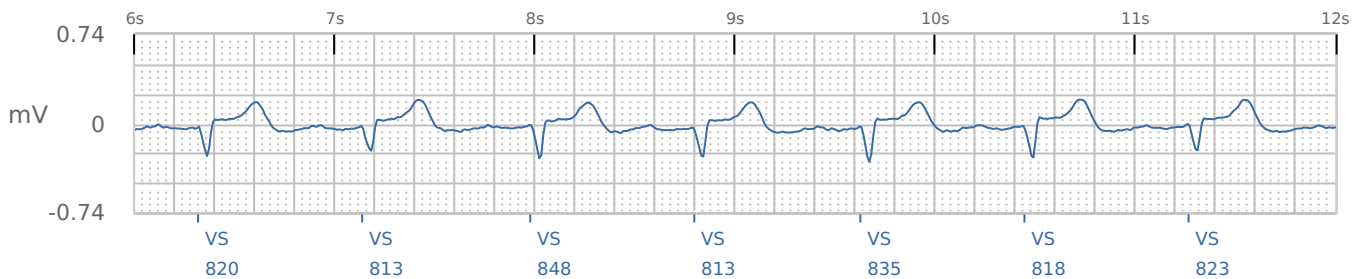
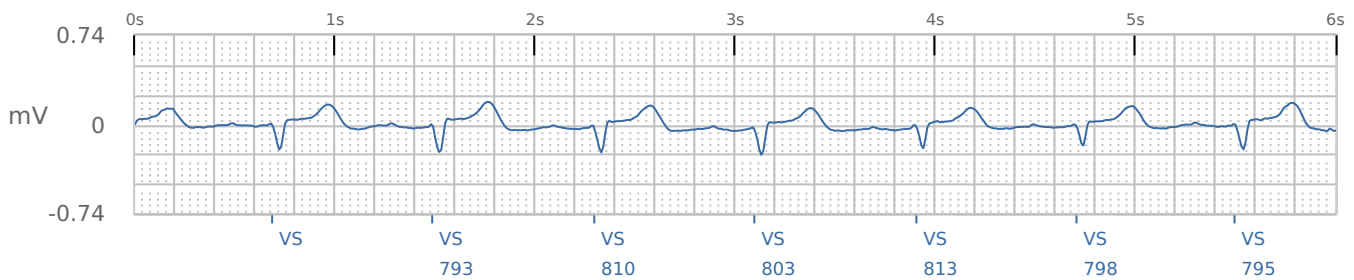
Clinical Context:
None

Event	Description	Date/Time	Duration	Rate	Assessment
P-2	Pause	Aug 26, 2020 05:00 CDT	8.8 s	--	Not Assessed

Pause Settings
 Duration 3 s
 Response Balanced



S-ECG displayed at 25mm per second

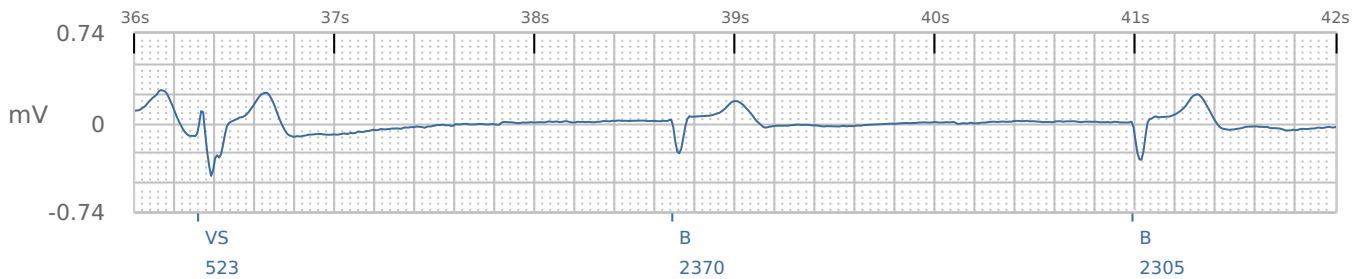
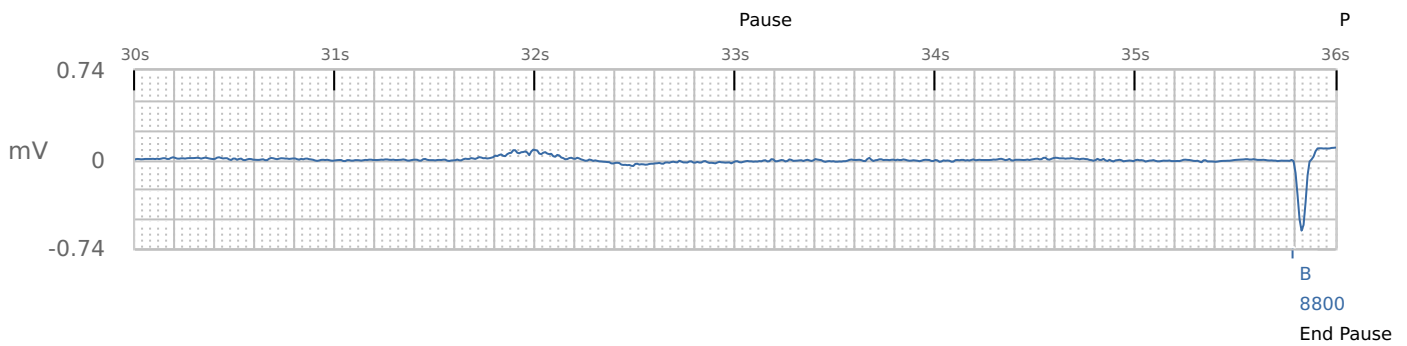
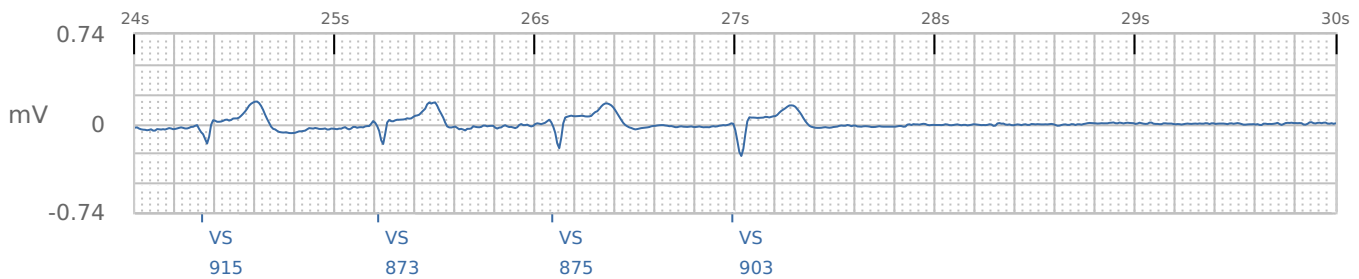
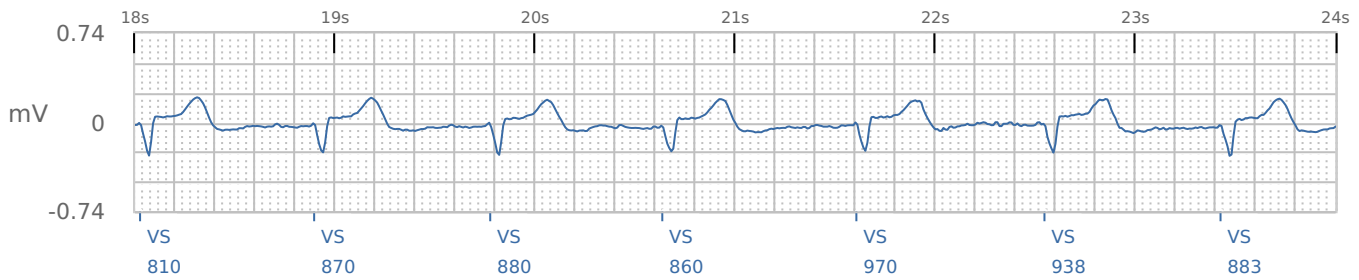
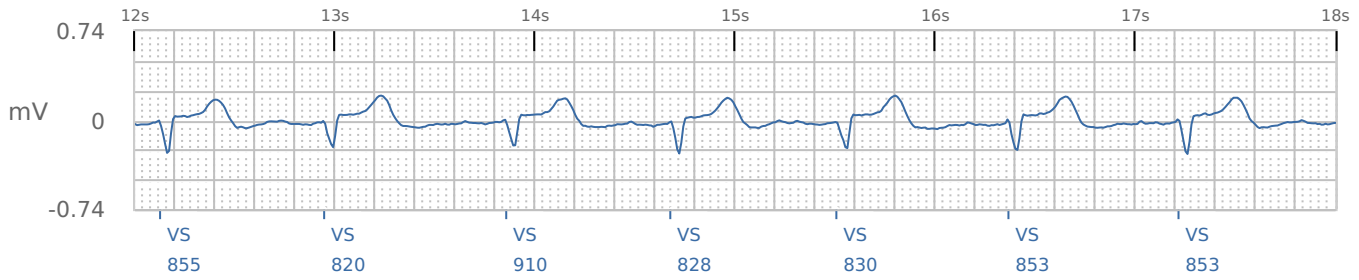


Comments & Interventions

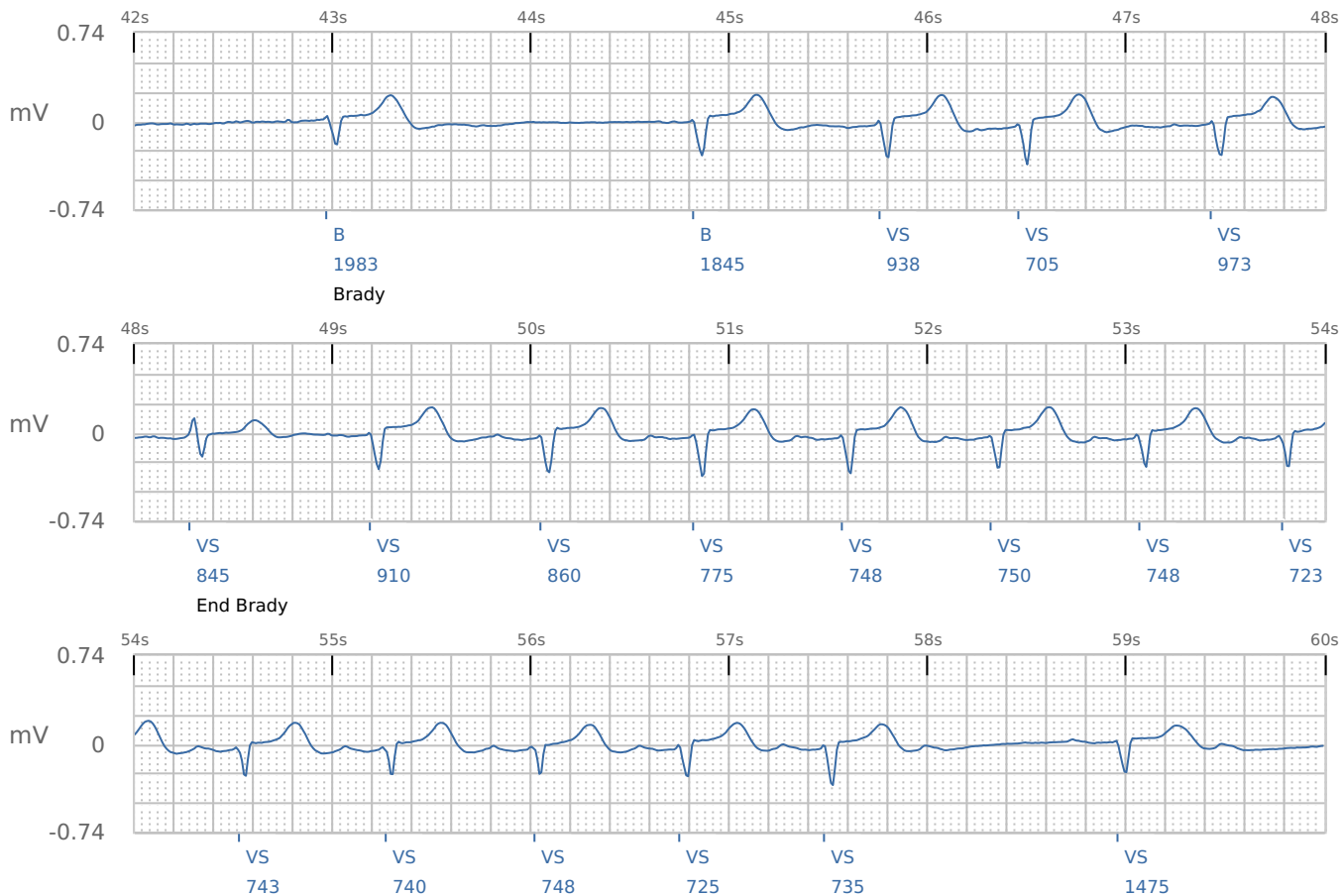
Signature

Date

Monitoring: Syncope



Monitoring: Syncope



PATIENT MONITORED FOR: Ventricular Tachycardia

DETAILS:

PVC induced non-sustained VT and return to normal sinus rhythm

- Monomorphic VT episode lasting 13 seconds (22 beats) with an average ventricular rate of 192 bpm, max V rate of 203 bpm.
- Occasional PVCs noted throughout the event.
- PVC inducing non-sustained VT at 14 seconds (report page 2).
- Return to NSR at 25 seconds (report page 2).
- These rates are calculated by the device and shown on the report.
- The threshold is programmed to the nominal of 170 bpm.

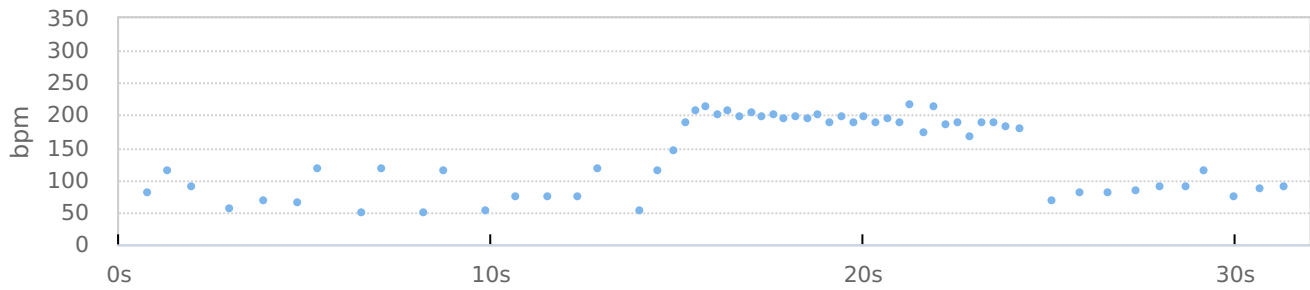


Reason For Monitoring
Ventricular Tachycardia

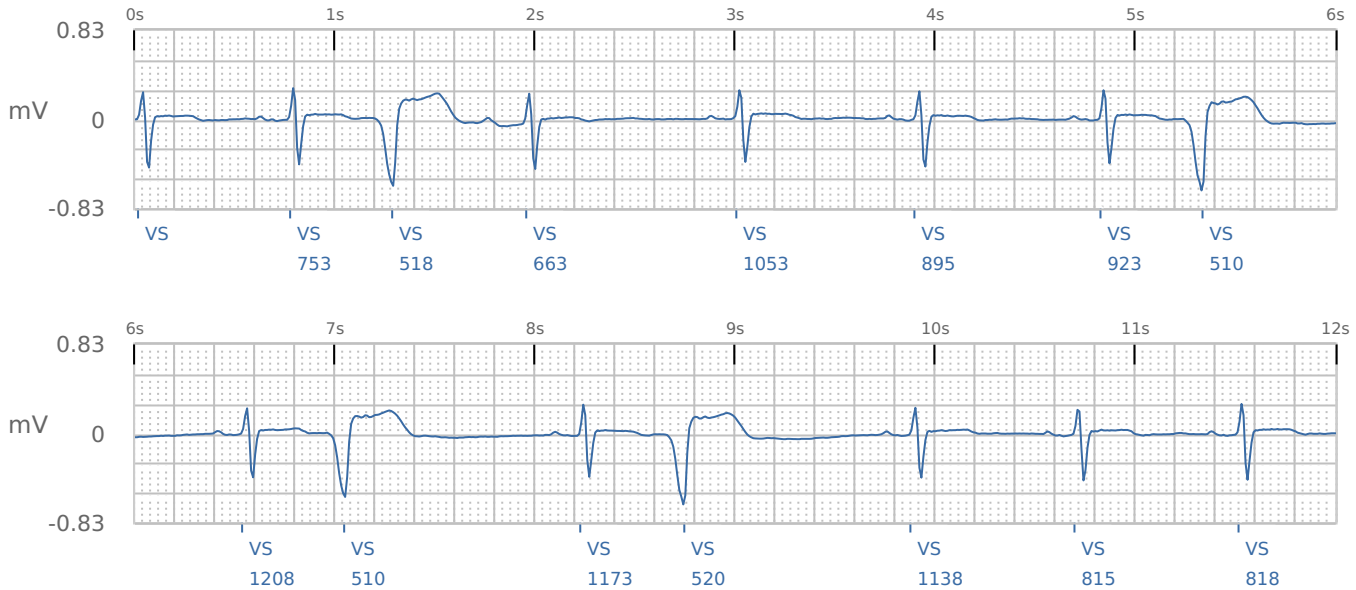
Clinical Context:
None

Event	Description	Date/Time	Duration	Rate	Assessment
T-1	Tachy (VT)	Sep 23, 2020 06:07 EDT	13 s	Avg 192 bpm Max 203 bpm	Not Assessed

Tachy Settings
 Rate 170 bpm
 Duration 5 s
 Response More
 Morphology Assessment On



S-ECG displayed at 25mm per second

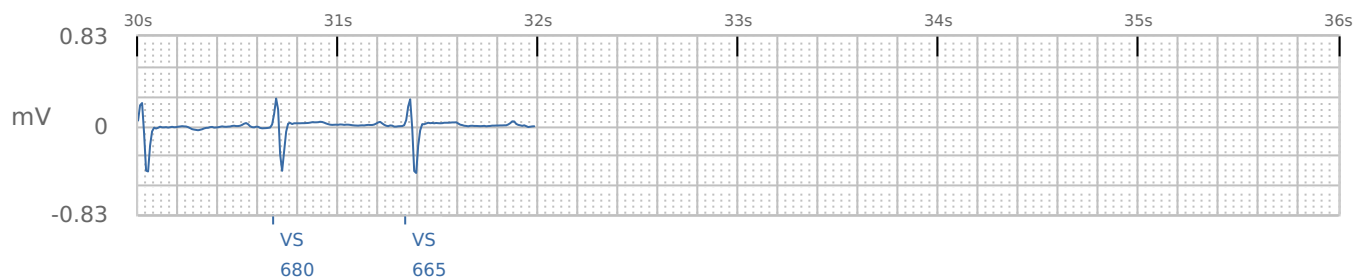
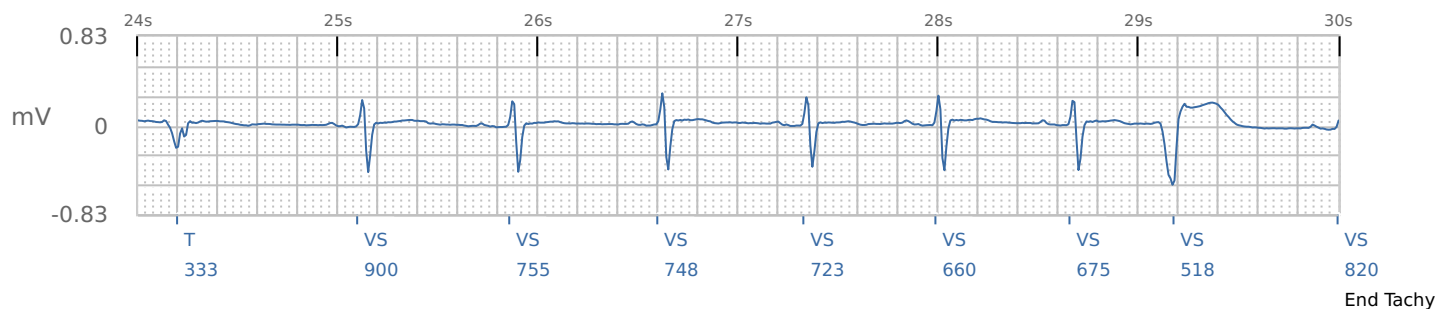
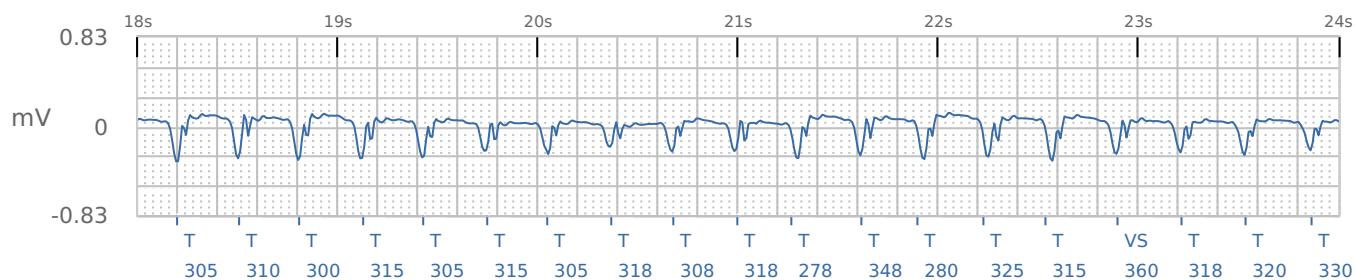
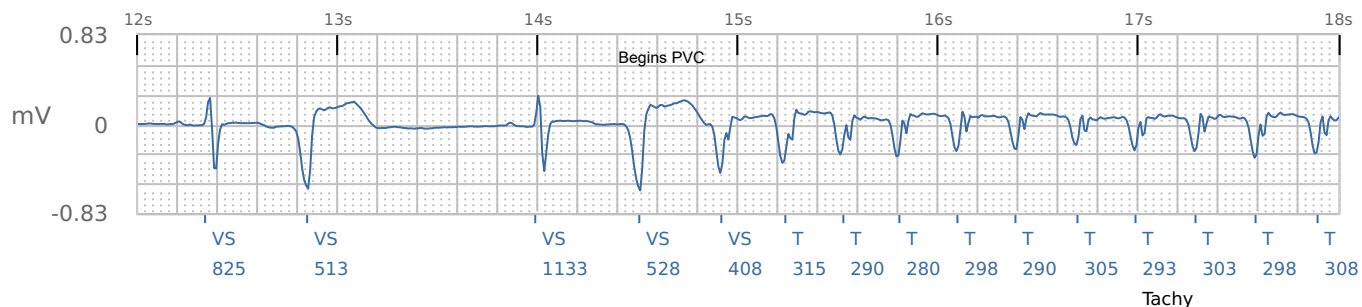


Comments & Interventions

Signature

Date

Monitoring: Ventricular Tachycardia



PATIENT MONITORED FOR: Syncope

DETAILS:

SVT event

- SVT episode lasting 6 minutes and 48 seconds with an average ventricular rate of 160 bpm, max V rate of 188 bpm.
- Episode begins at 12 seconds (report page 2).
- These rates are calculated by the device and shown on the report.
- Clinic adjusted the nominal Tachy settings for a syncope patient from a nominal rate of 170 bpm to 150 bpm.

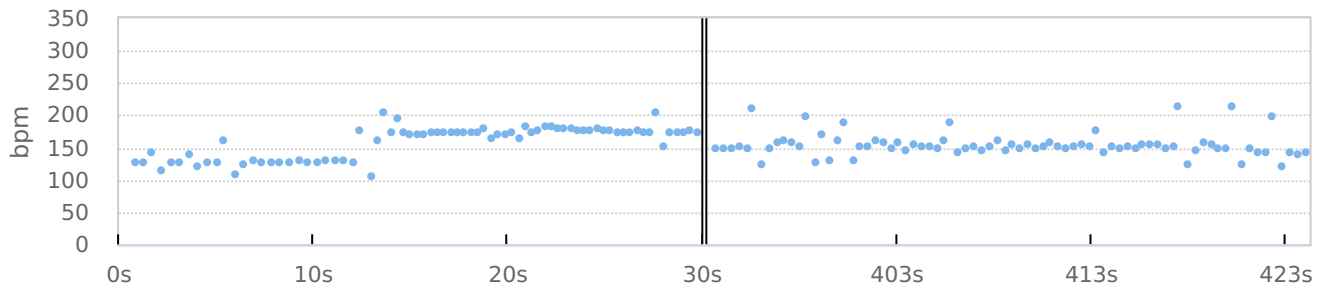


Reason For Monitoring
Syncope

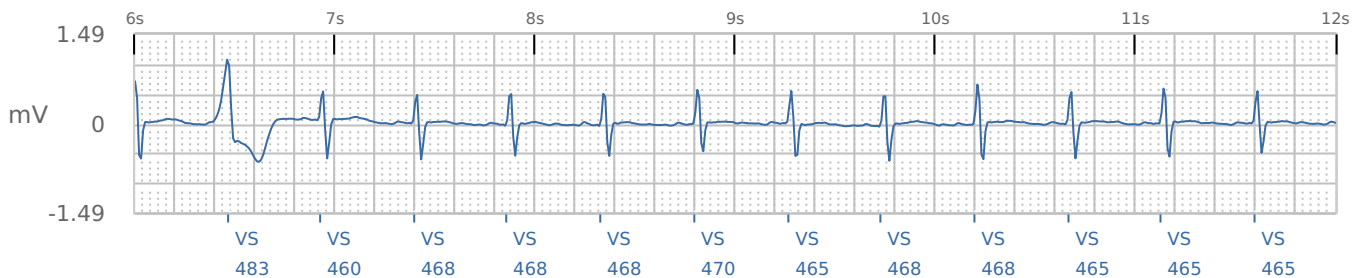
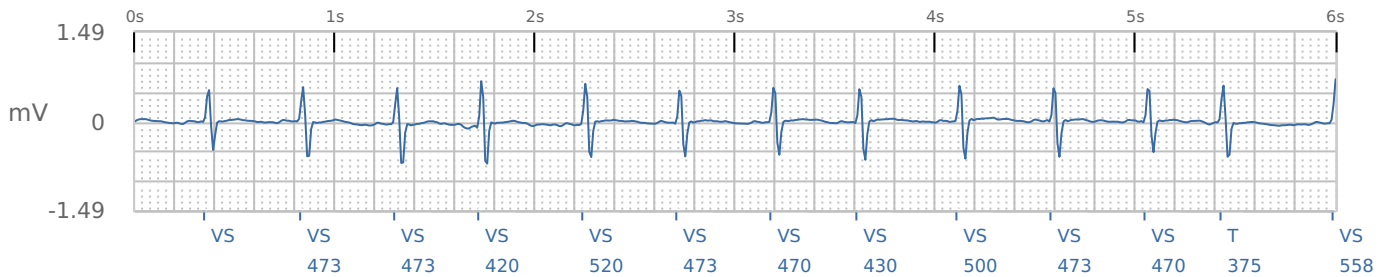
Clinical Context:
None

Event	Description	Date/Time	Duration	Rate	Assessment
T-37	Tachy (SVT)	Sep 04, 2020 06:20 EDT	6 m 48 s	Avg 160 bpm Max 188 bpm	Not Assessed

Tachy Settings
 Rate 150 bpm
 Duration 5 s
 Response More
 Morphology Assessment On



S-ECG displayed at 25mm per second

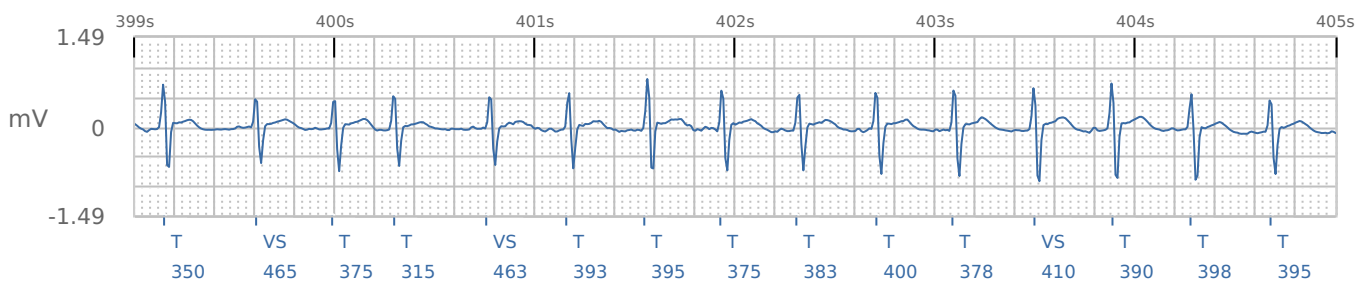
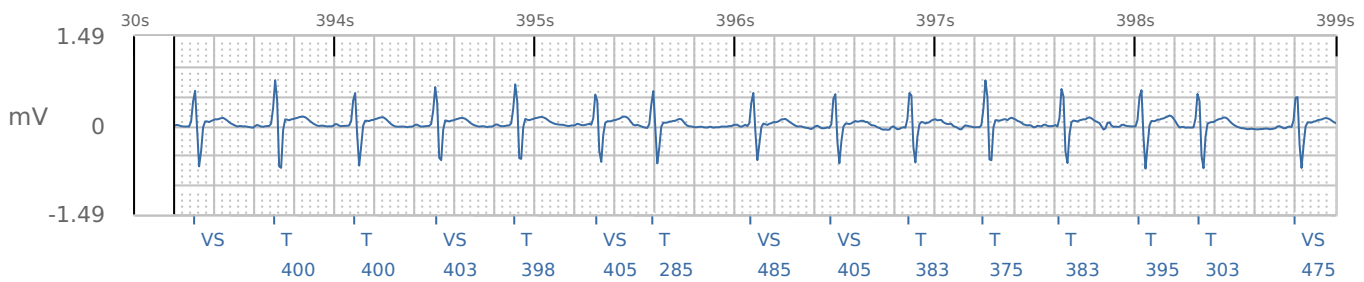
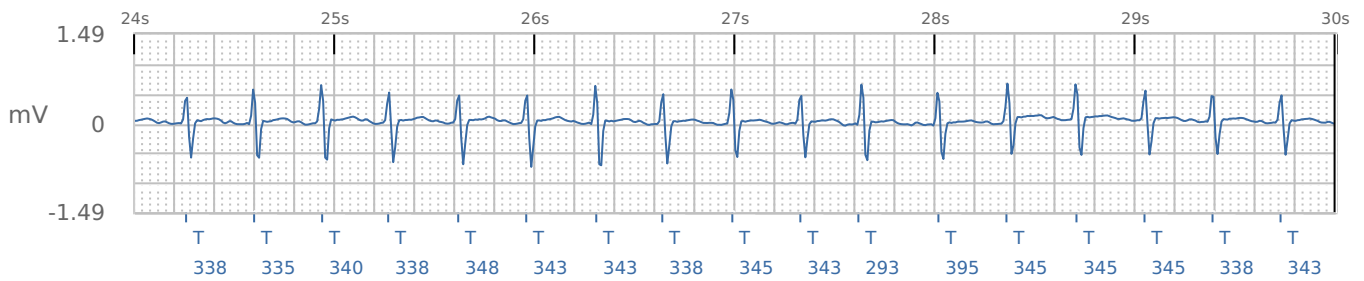
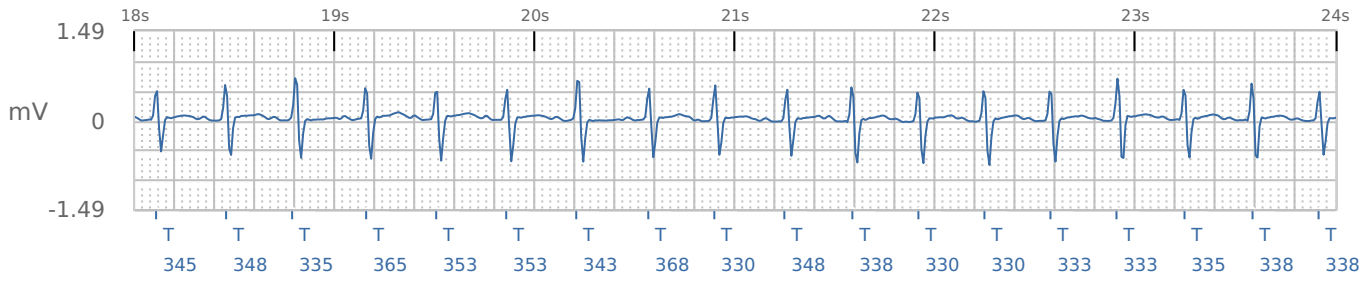
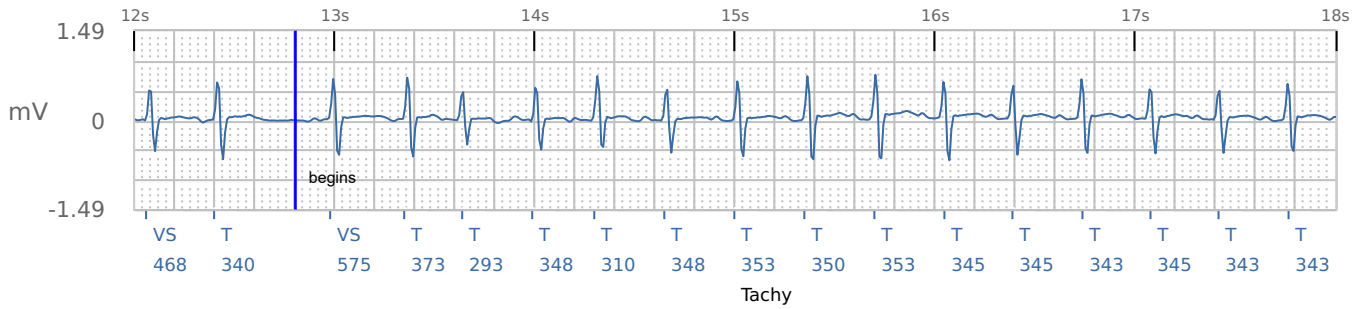


Comments & Interventions

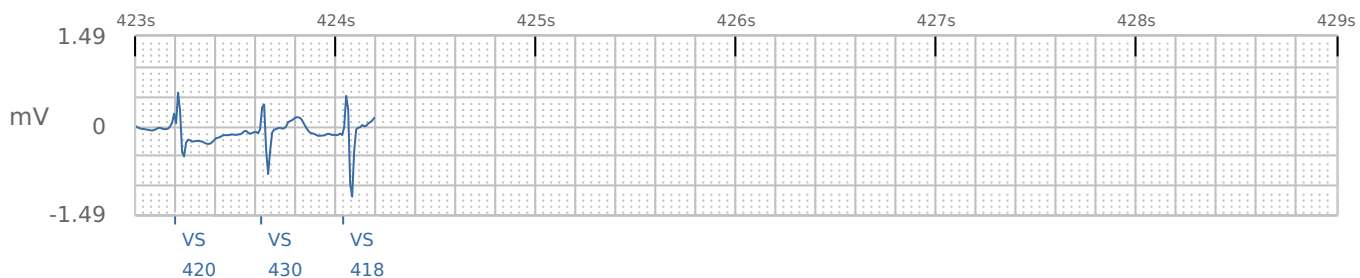
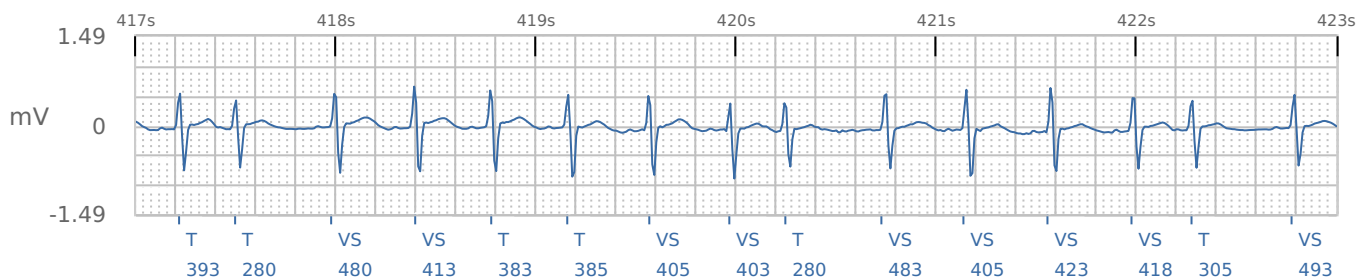
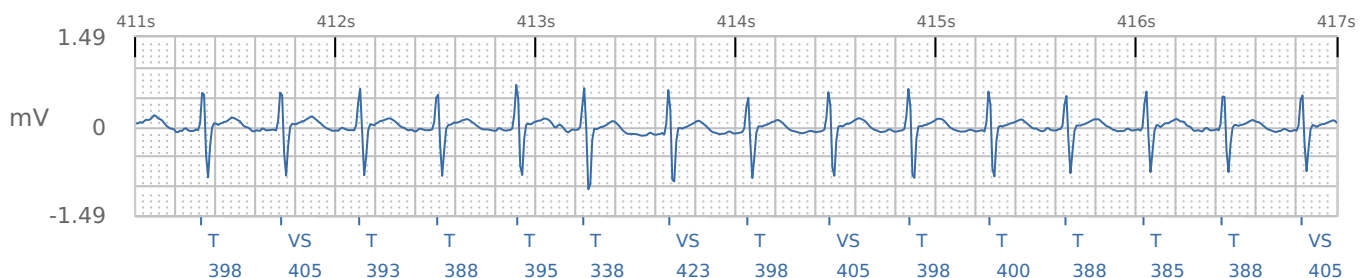
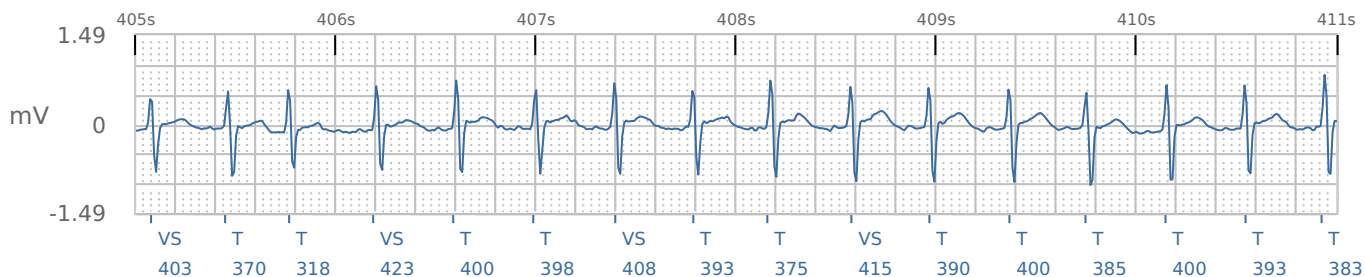
Signature

Date

Monitoring: **Syncope**



Monitoring: **Syncope**



End Tachy

PATIENT MONITORED FOR: AF Management

DETAILS:

SVT episode and return to normal sinus rhythm

- SVT episode lasting 14 seconds (14 beats) with an average ventricular rate of 160 bpm, max V rate of 169 bpm.
- Around 23 seconds, the SVT returns to NSR (report page 2).
- These rates are calculated by the device and shown on the report.
- The clinic adjusted the nominal Tachy settings for an AF Management patient from a nominal rate of 170 bpm to 150 bpm.

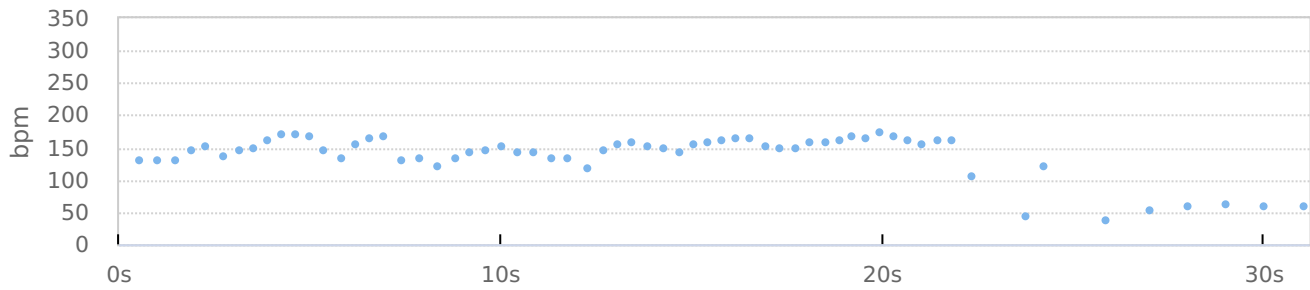


Reason For Monitoring
AF Management

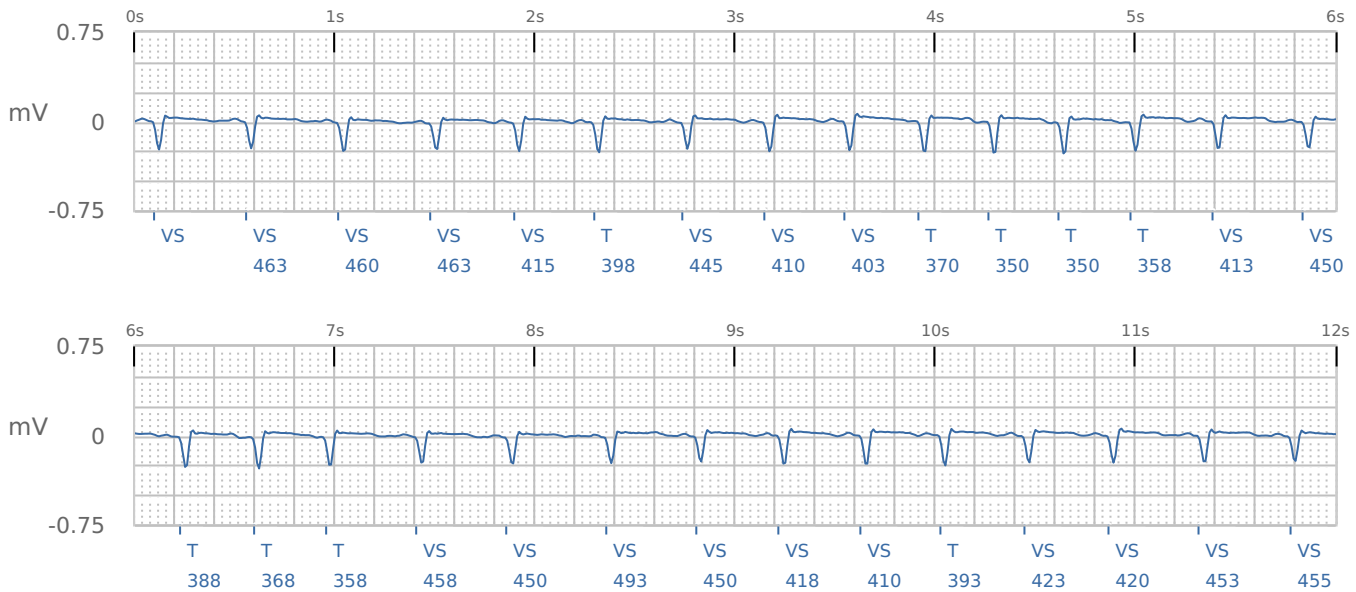
Clinical Context:
None

Event	Description	Date/Time	Duration	Rate	Assessment
T-181	Tachy (SVT)	Nov 29, 2020 08:07 PST	14 s	Avg 160 bpm Max 169 bpm	Not Assessed

Tachy Settings
 Rate 150 bpm
 Duration 5 s
 Response Less
 Morphology Assessment On



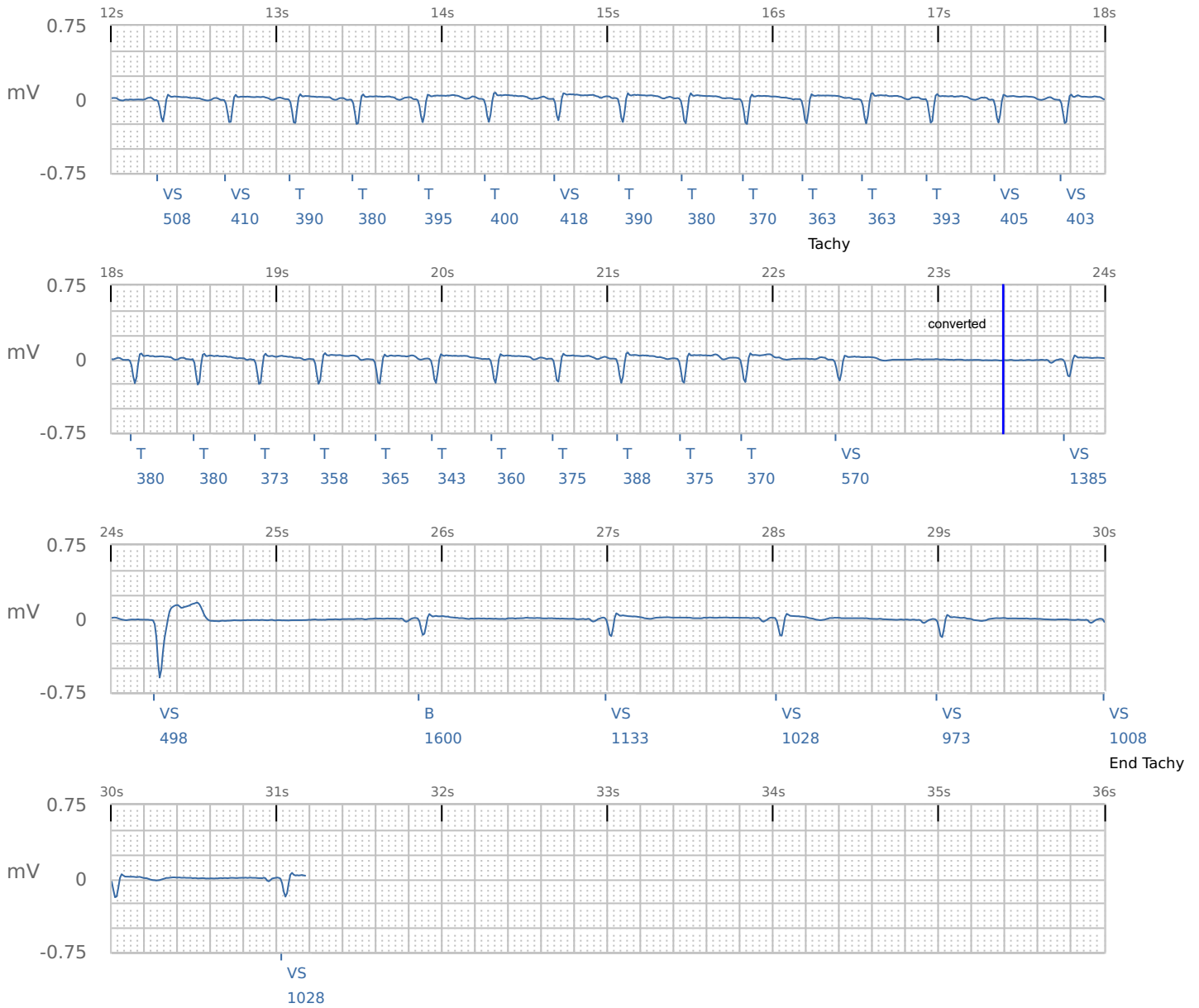
S-ECG displayed at 25mm per second



Comments & Interventions

Signature

Date



PATIENT MONITORED FOR: Suspected AF

DETAILS:

Sustained AT with regular V to V rhythm and consistent rate

- Atrial rate of 145 bpm during the 10 hour and 16 minute AT episode.
- AT settings were programmed to nominal.

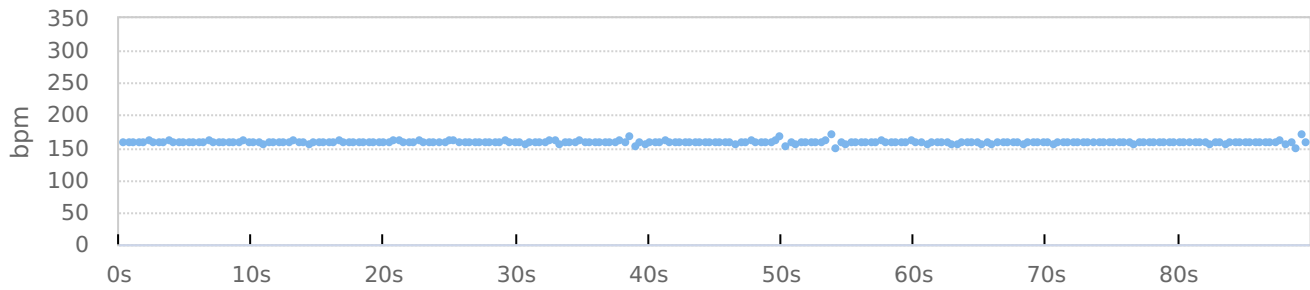


Reason For Monitoring
Suspected AF

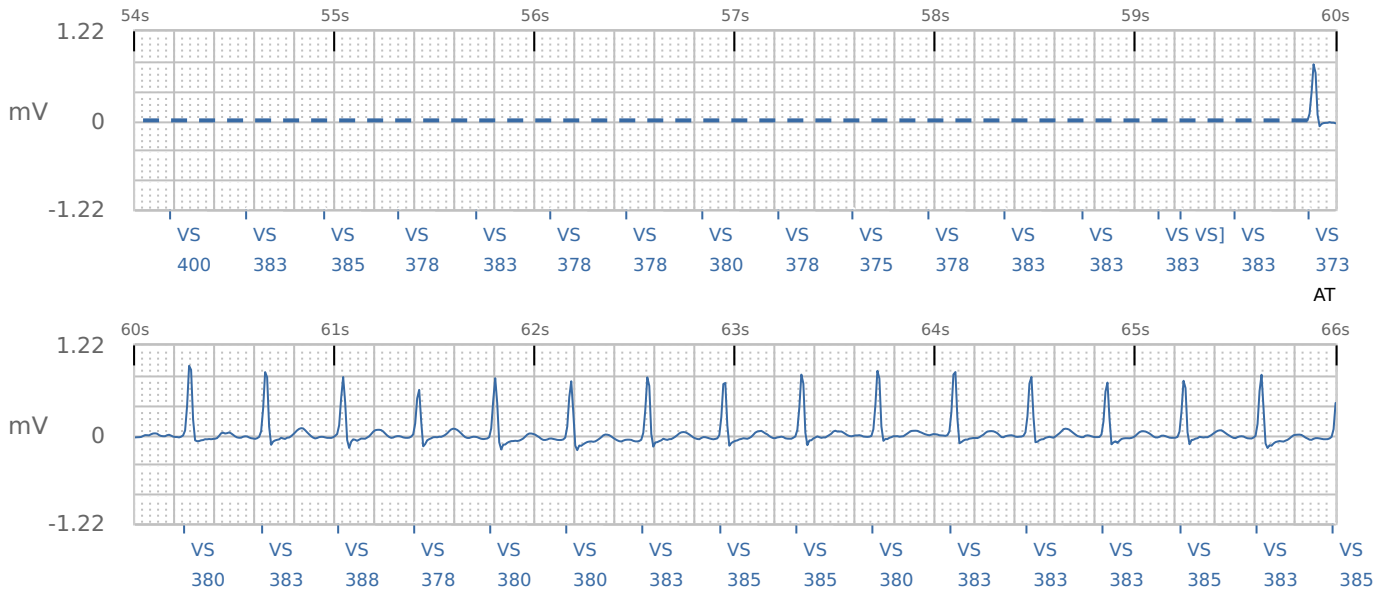
Clinical Context:
None

Event	Description	Date/Time	Duration	Rate	Assessment
AT-10	AT	Aug 04, 2020 09:18 EDT	10 h 16 m	Avg 145 bpm	Not Assessed

AT Settings
Rate 110 bpm
Duration 4 hrs



S-ECG displayed at 25mm per second



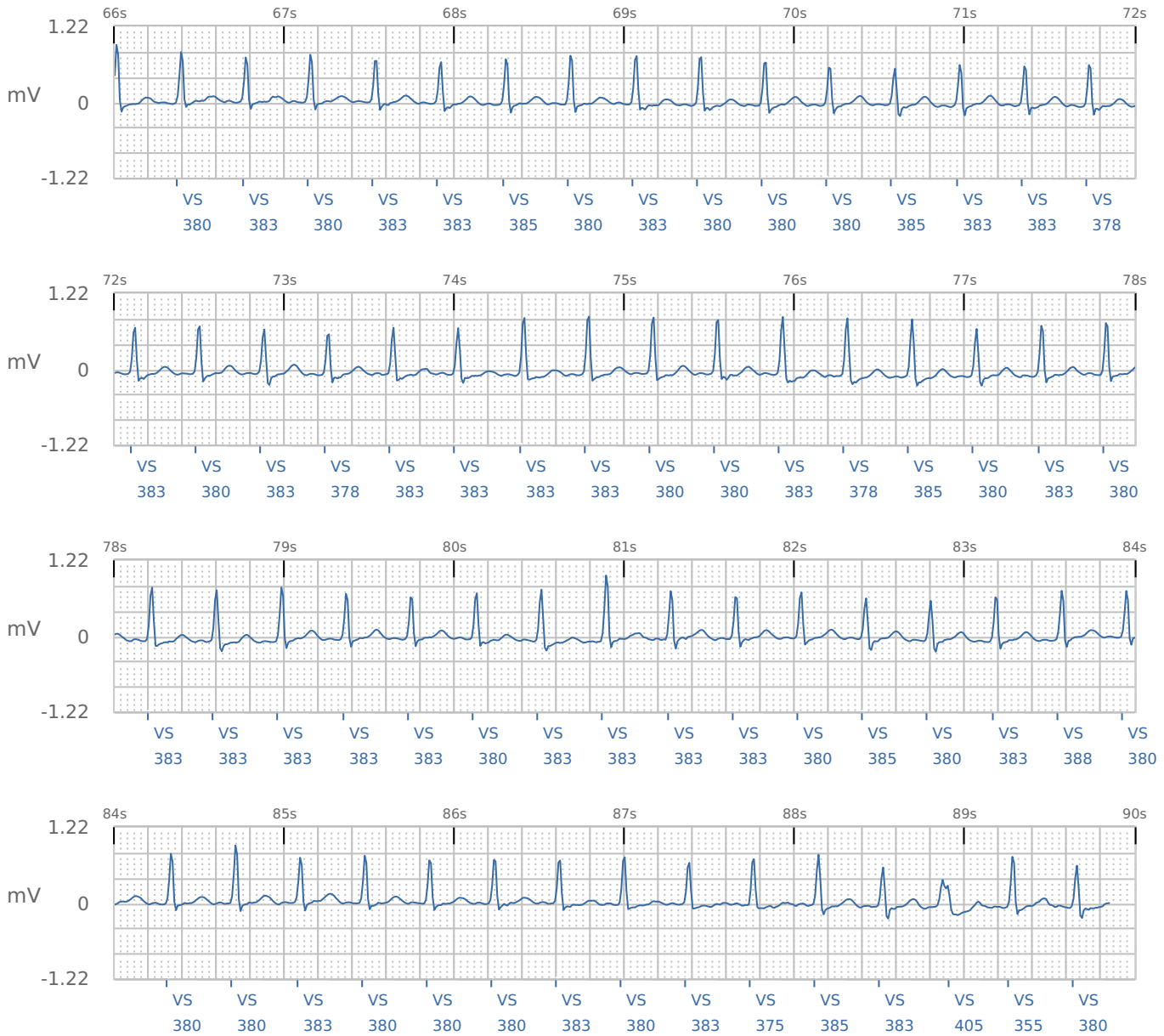
Comments & Interventions

Signature

Date

ID:

Monitoring: Suspected AF



PATIENT MONITORED FOR: Cryptogenic Stroke

DETAILS:

P-waves during brady event

- At 11:34AM, bradycardia event with an average rate of 40 bpm over the 12 second duration of the event.
- P-waves are visible throughout the event.

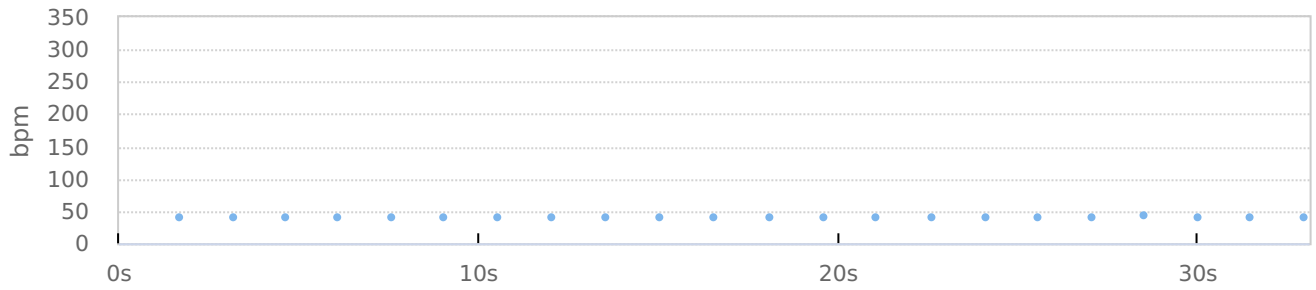


Reason For Monitoring
Cryptogenic Stroke

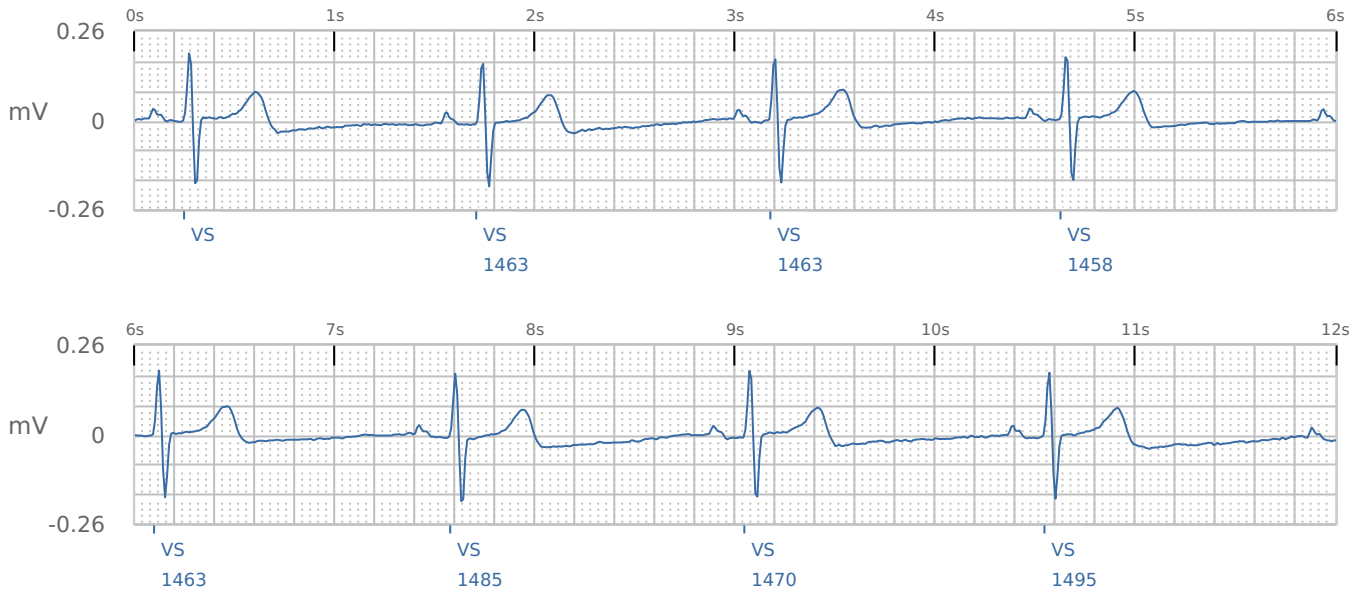
Clinical Context:
None

Event	Description	Date/Time	Duration	Rate	Assessment
B-1	Brady	Jul 12, 2020 11:34 EDT	12 s	Avg 40 bpm	Appropriate

Brady Settings Duration 1 s
 Rate 40 bpm



S-ECG displayed at 25mm per second



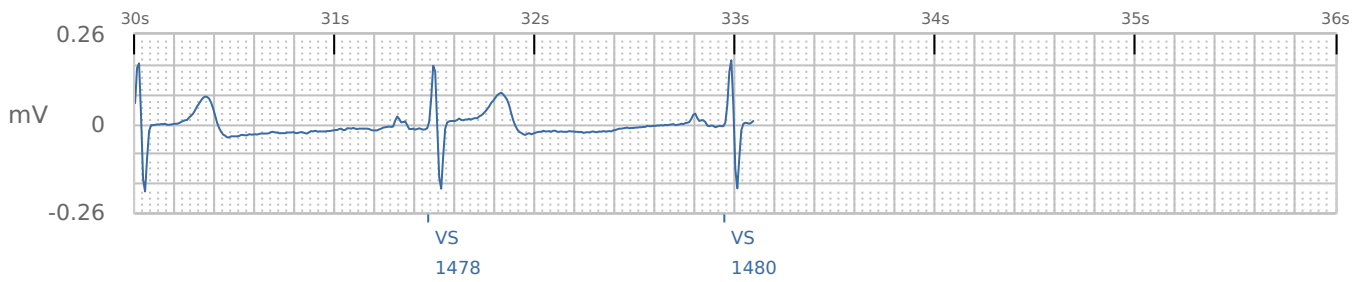
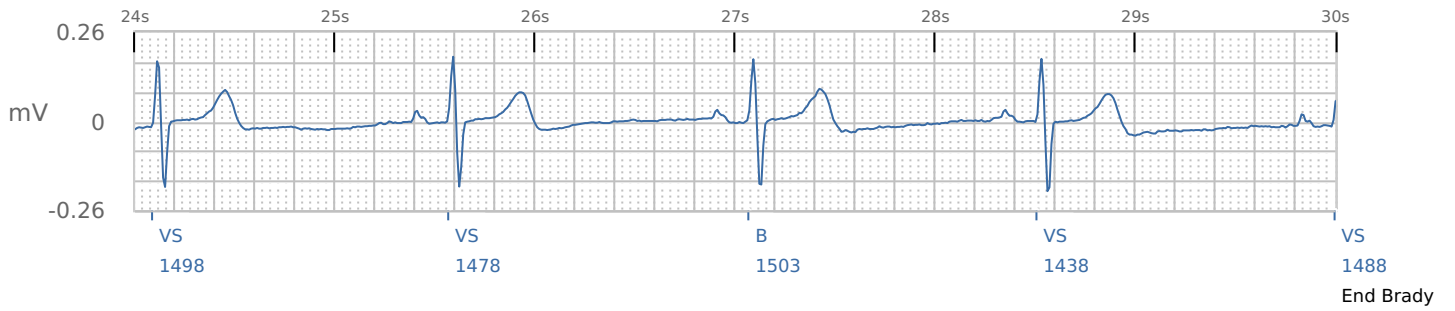
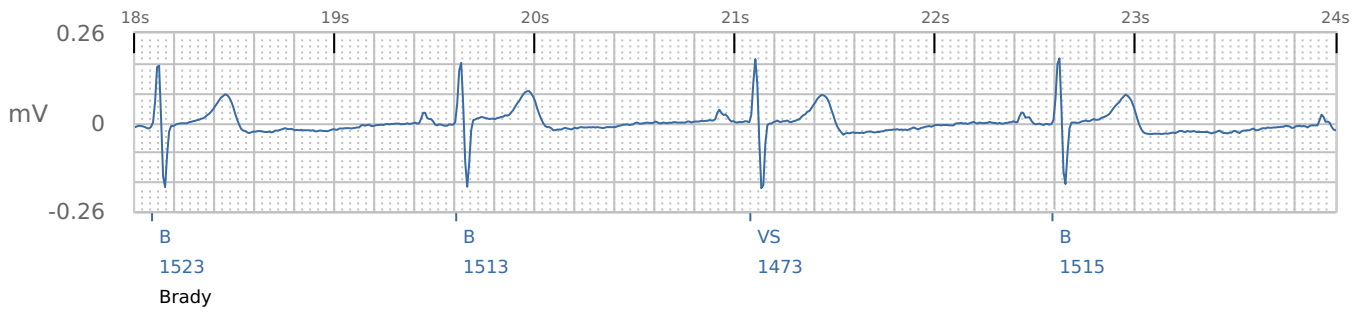
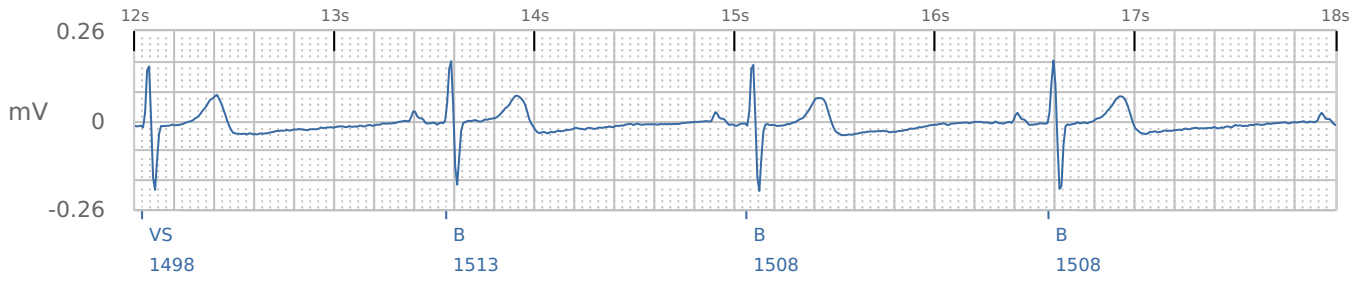
Comments & Interventions

Signature

Date

ID:

Monitoring: Cryptogenic Stroke



PATIENT MONITORED FOR: Cryptogenic Stroke

DETAILS:

2:1 HB during brady event

- At 9:11PM, bradycardia event with an average rate of 37 bpm over the 5 second duration of the event.
- Clinic entered "2:1 HB" in the notes section of the event report header.
- Starting at 19 seconds (report page 2), P-waves can be seen in support of a 2:1 HB during the brady event.
- R-waves are clipped as the clinic zoomed in on the S-ECG to see p-waves.



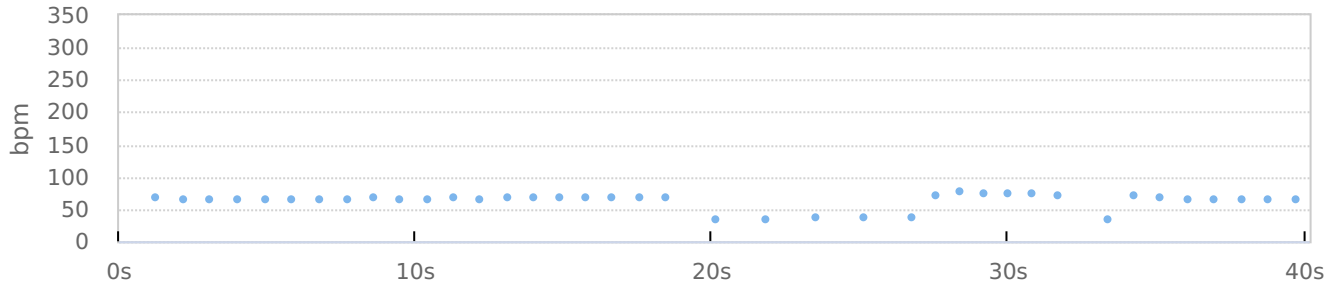
Reason For Monitoring
Cryptogenic Stroke

Clinical Context:
None

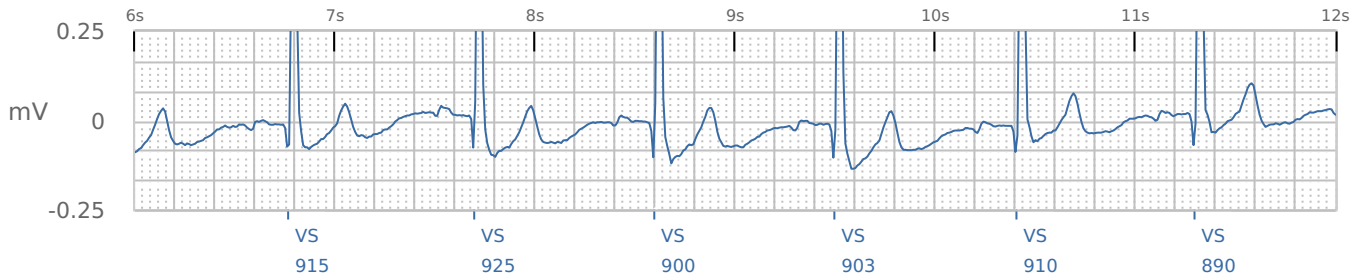
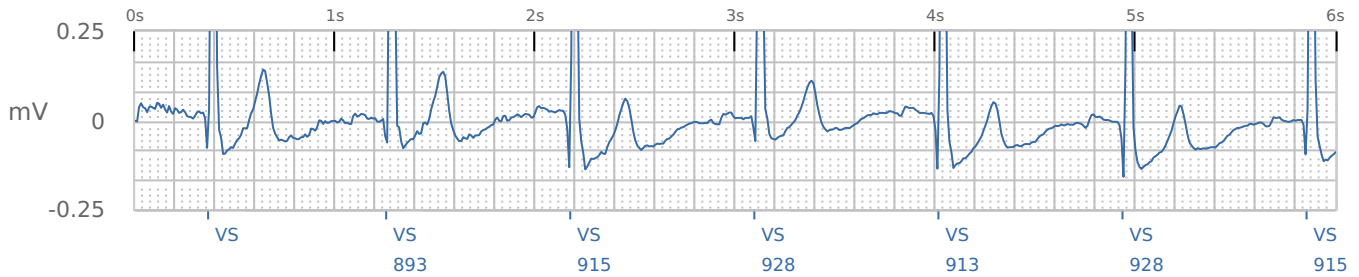
Event	Description	Date/Time	Duration	Rate	Assessment
B-1	Brady	Aug 12, 2020 21:11 MDT	5 s	Avg 37 bpm	Appropriate

2:1 HB, clinic alerted

Brady Settings Duration 1 s
 Rate 40 bpm



S-ECG displayed at 25mm per second

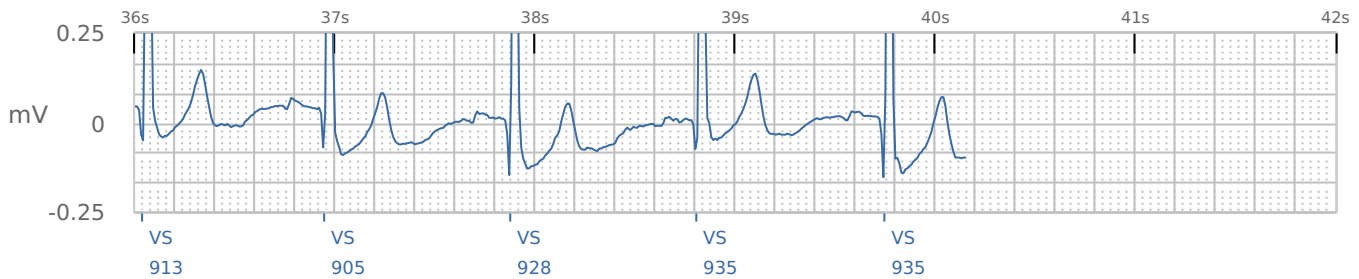
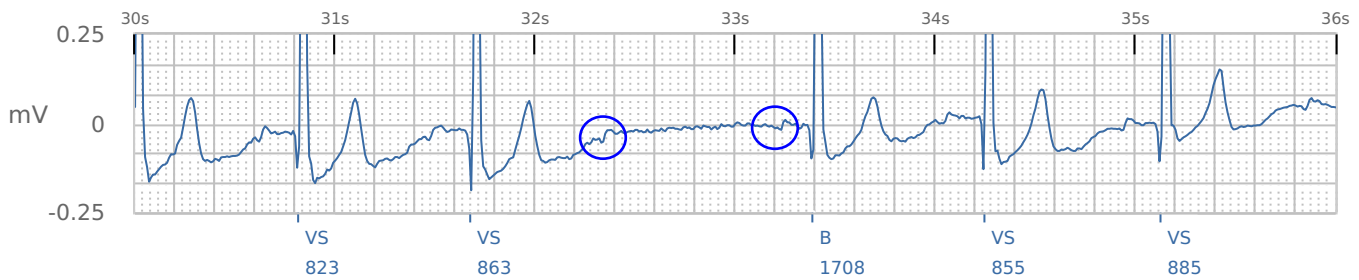
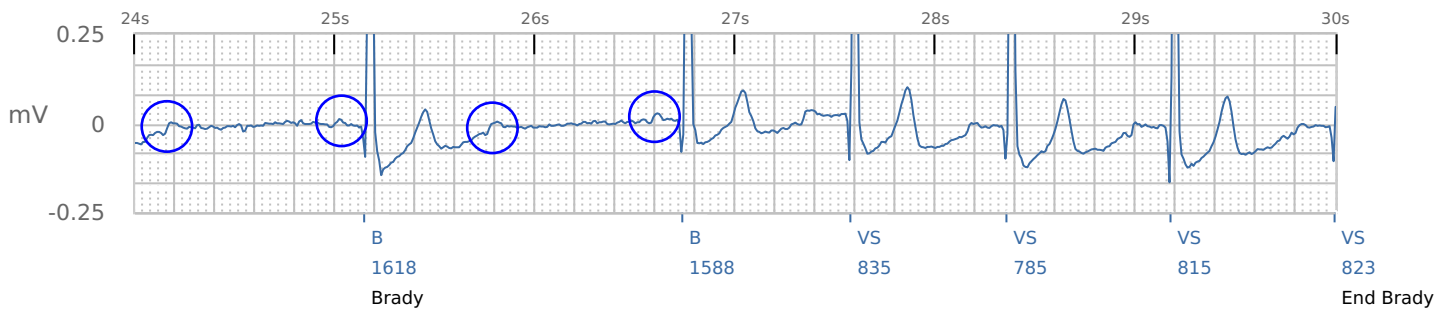
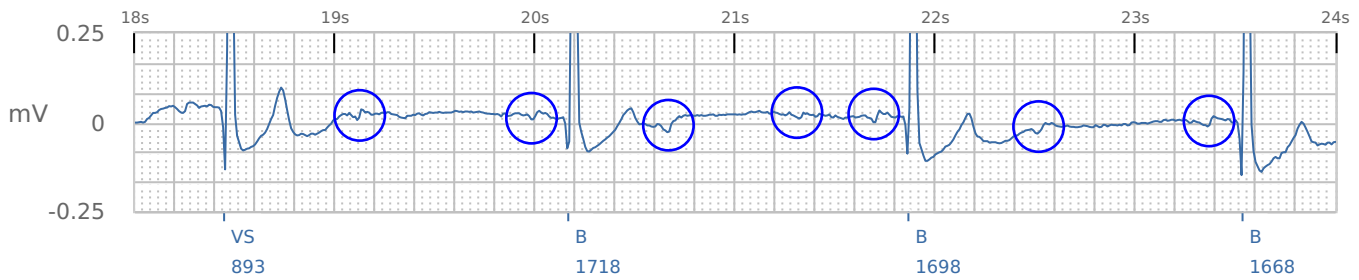
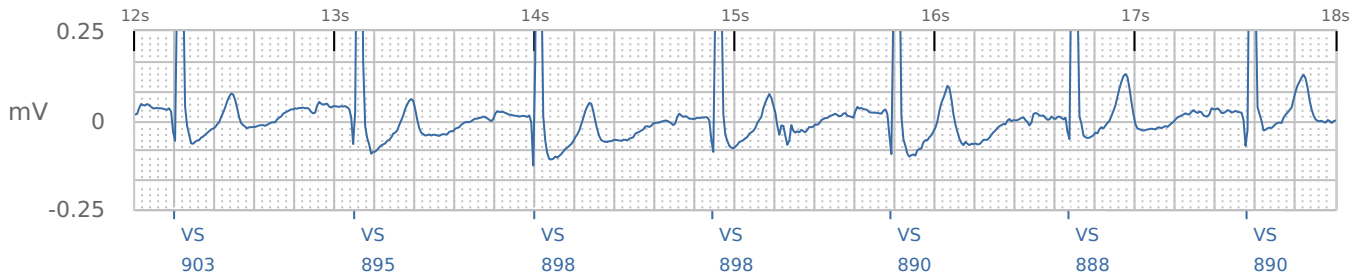


Comments & Interventions

Signature

Date

Monitoring: Cryptogenic Stroke



PATIENT MONITORED FOR:
Cryptogenic Stroke

DETAILS:

Presenting strip with P-waves



ID:

DOB:

Monitoring: **Cryptogenic Stroke**

AF Overview

AF Burden

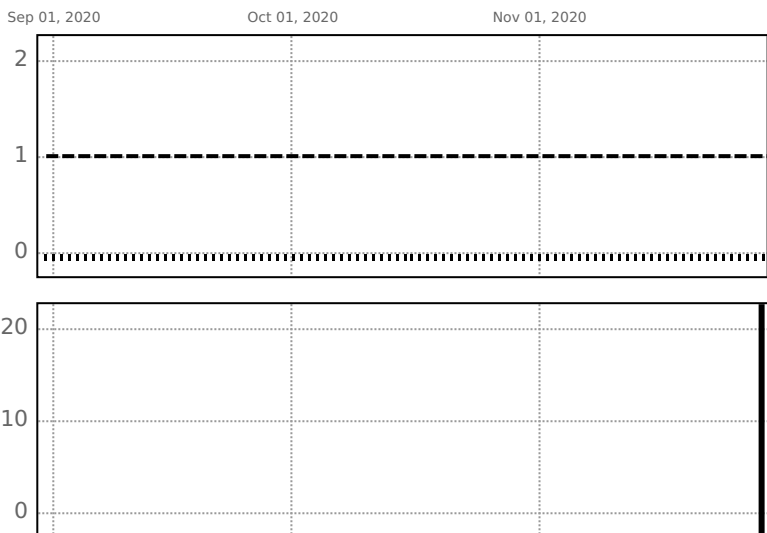
--- Threshold

Nov 30, 2020
0.0
 hour(s)

V Rate during AF

█ Max
 █ Mean

Nov 29, 2020
 N/R
 N/R
 bpm



	Recent	Previous
	Oct 29, 2020 - Nov 30, 2020 <i>33 day(s)</i>	Sep 22, 2020 - Oct 29, 2020 <i>38 day(s)</i>
Total Time in AF	0 % (0 m)	0 % (0 m)
# of AF Events	0	0
Longest AF	N/A	N/A

ID: Device: M301 LUX-Dx™
Gender: Implant Date:
DOB: Implanted By:
Phone: Followed By:
Clinic: Patient Group:

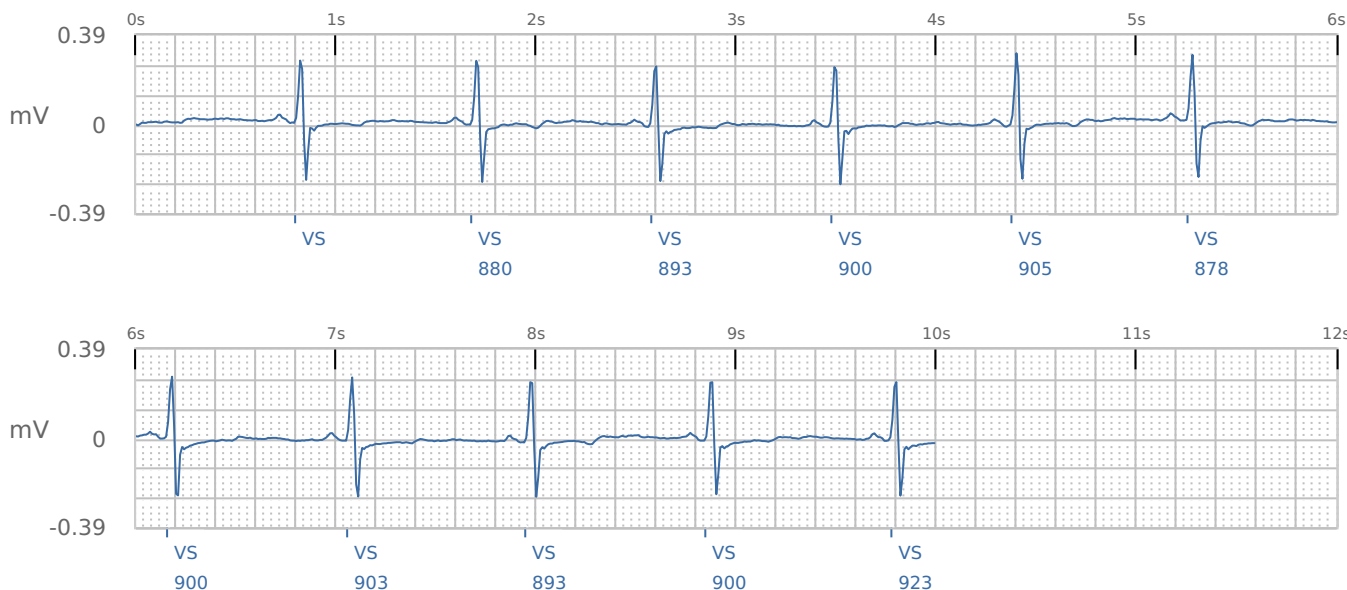
Reason For Monitoring
Cryptogenic Stroke

Clinical Context:
None

Date/Time: Dec 16, 2020 07:59 EST

Avg Rate: 67 bpm

S-ECG displayed at 25mm per second



PATIENT MONITORED FOR: Cryptogenic Stroke

DETAILS:

P-waves in presenting strip for a patient with runs of AF

- Visible P-waves in the presenting S-ECG could make adjudicating the AF events easier
- 69 AF events that were ≥ 2 minutes; 1% AF burden.
- The average heart rate is included in the longest AF detected episode.
- For the date highlighted (Dec 16) by the black bar on the report, the rate plot during AF shows the patient's mean V Rate during AF was relatively controlled, 76 bpm and the max was 104.



ID:

DOB:

Monitoring: **Cryptogenic Stroke**

AF Overview

AF Burden

--- Threshold

Dec 17, 2020

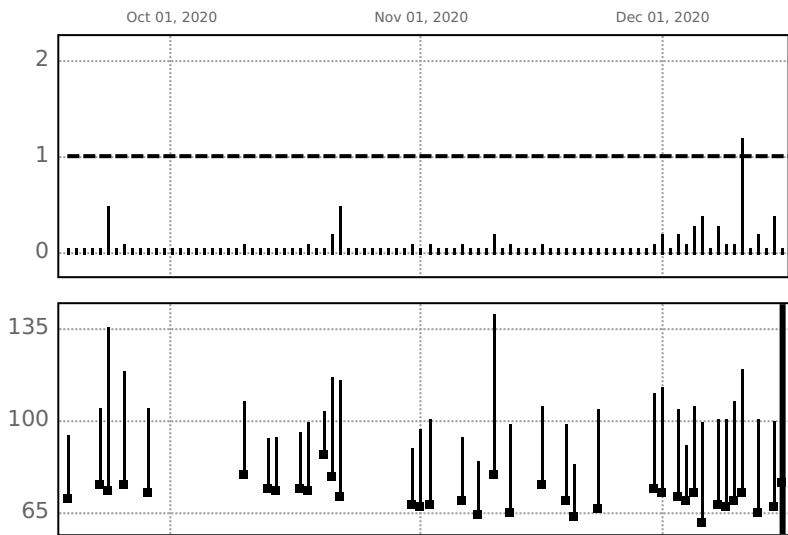
0.0
hour(s)

V Rate during AF

▮ Max
▮ Mean

Dec 16, 2020

104
76
bpm



Recent

Previous

Nov 30, 2020 - Dec 17, 2020
18 day(s)

Sep 08, 2020 - Nov 30, 2020
84 day(s)

Total Time in AF

1 %
(3 h 40 m)

< 1 %
(2 h 46 m)

of AF Events

69

69

Longest AF

16 m
(Avg 70 bpm)

10 m
(Avg 69 bpm)

LUX-Dx™ Insertable Cardiac Monitor System

CAUTION: Federal law (USA) restricts this device to sale by or on the order of a physician. Rx only. Prior to use, please see the complete "User's Manual" for more information on Indications, Contraindications, Warnings, Adverse Events, and Operator's Instructions.

INDICATIONS

The LUX-Dx™ Insertable Cardiac Monitor (ICM) is intended to monitor and record subcutaneous electrocardiogram (S-ECG). The recorded S-ECG is used for the clinical evaluation and diagnosis of cardiac arrhythmias. The LUX-Dx is indicated for use in patients that have a known heart condition and are at risk of developing an abnormal heart rhythm, or have symptoms that may suggest a cardiac arrhythmia, such as dizziness, palpitations, syncope, chest pain, and/or shortness of breath. The LUX-Dx has not been tested specifically for pediatric use.

CONTRAINDICATIONS

There are no known contraindications for the insertion of the LUX-Dx insertable cardiac monitor. However, the patient's particular medical condition may dictate whether or not they can tolerate a subcutaneous, chronically-inserted device. LATITUDE Clarity is contraindicated for use with any device other than a compatible Boston Scientific device.

WARNINGS

Concomitant use of the ICM system and implanted electro-mechanical devices [for example implantable neuromodulation/neurostimulation systems, ventricular assist device (VAD), or implantable insulin pump or drug pump] can result in interactions that could compromise the function of the ICM, the co-implanted device, or both. Electromagnetic interference (EMI) or therapy delivery from the co-implanted device can interfere with ICM sensing and/or rate assessment, resulting in failure to monitor or record when needed. Verify sensing configuration, operation modes, surgical considerations and existing placement of all involved devices prior to any co-implant. To help prevent undesirable interactions, test the ICM system when used in combination with the co-implanted device.

Do not expose a patient with an ICM system to diathermy. The interaction of diathermy therapy with an insertable cardiac monitor can damage the device and cause patient injury. The influence of medical equipment on implanted devices varies considerably according to the type of unit and energy levels employed. In situations where the risks are known, always interrogate the device and save data before the procedure, and check device function afterwards.

Magnet model 6386 has been tested for use with the ICM system. Use of any other magnets has not been tested and could result in failure to initiate communication with the device. The magnet provided with the ICM system may cause interference with devices sensitive to magnetic fields such as hearing aids, pacemakers, and other implanted devices. It can also permanently disable some magnetic strip cards.

Keep the magnet at least 15 cm (6 inches) away from items sensitive to magnetic fields, including the ICM device when the magnet is not being used to initiate communication between the device and the patient or clinic app.

The mobile devices and magnet are MR Unsafe and must remain outside the MRI site Zone III (and higher) as defined by the American College of Radiology Guidance Document for Safe MR Practices.

Unless all of the MRI Conditions of Use are met, MRI scanning of the patient does not meet MR Conditional requirements for the inserted device, and significant harm to or death of the patient and/or damage to the inserted device may result.

Scanning patients who have other MR Conditional devices is acceptable if all the MR Conditional requirements for each of the implanted devices are met. Do not conduct an MRI scan if any conditions or implants prohibit it.

Advise patients to seek medical guidance before entering environments that could adversely affect the operation of the active implantable medical device, including areas protected by a warning notice that prevents entry by patients.

PRECAUTIONS

For specific information on precautions, refer to the following sections of the product labeling: General, Clinical Considerations, Sterilization and Storage, Insertion, Magnet, Device Programming, Environmental and Medical Hazards, Follow-up, Device Removal and Disposal.

POTENTIAL ADVERSE EVENTS

Potential adverse events related to insertion of the device may include, but are not limited to, the following:

- Device migration
- Erosion
- Foreign body rejection phenomena
- Formation of hematomas or seromas
- Infection
- Local tissue reaction
- Tissue damage

For a list of potential adverse events associated with MRI scanning, refer to the MRI Technical Guide.

If any adverse events occur, invasive corrective action and/or ICM system modification or removal may be required.

92496928 (Rev. B)

